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The Male Latex Condom

Specification & Guidelines for Condom Procurement



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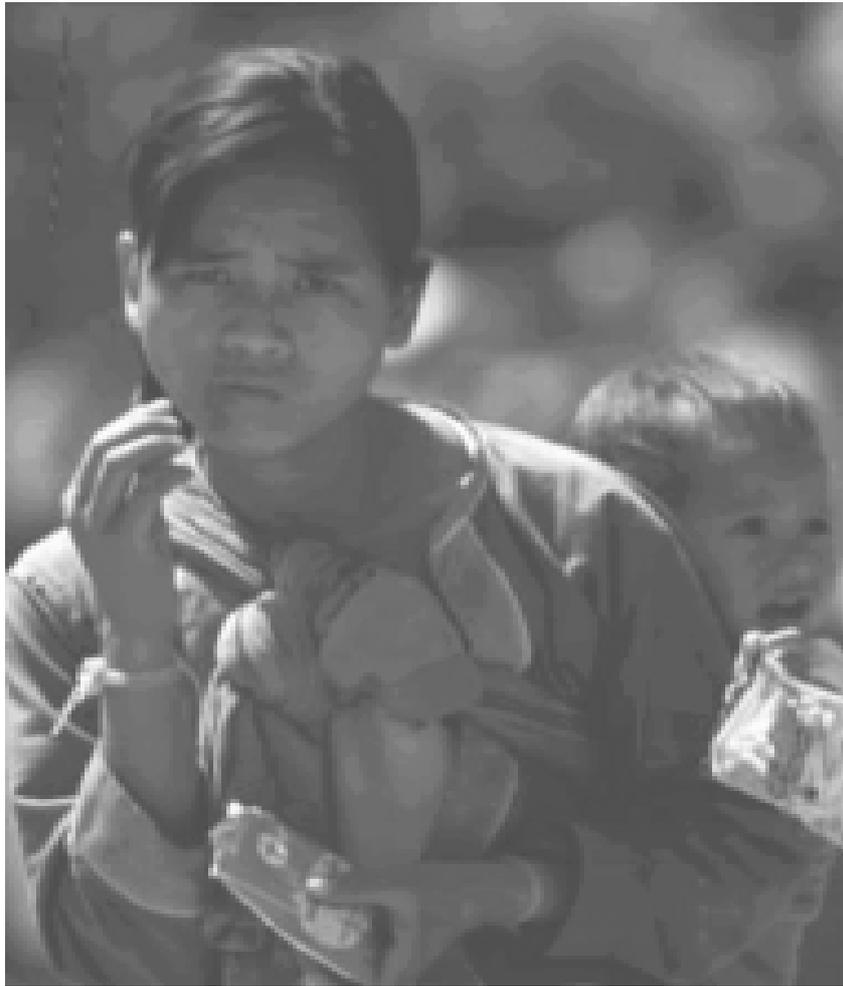


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Specification & Guidelines for Condom Procurement

Foreword

One of the most practical and effective means of protection against unwanted pregnancies and the transmission of sexually transmitted diseases (STDs) is the familiar natural latex male condom. Evidence suggests that, if used consistently and correctly, the male latex condom is an effective contraceptive that has no systemic side-effects and is an effective means of protection against STDs, including the human immune deficiency virus (HIV) that causes AIDS.

Therefore, latex condoms are of prime importance in the fight to stop the spread of AIDS.

Good quality natural latex condoms, when used consistently and correctly, are an effective means of protecting users and their partners against unwanted pregnancy and sexually transmitted diseases (STDs), including HIV that causes AIDS.

The condom did not command a great deal of scientific attention until in the 1980s it became clear that HIV was transmitted sexually. The scientific community then focused its attention on ensuring that condoms were of a high enough quality to provide adequate protection against unwanted pregnancies and STDs. The World Health Organization (WHO) was supported by the family planning and worldwide AIDS prevention community in its efforts to advocate for the development of new and more rigorous standards of quality for the production and distribution of condoms, and for more effective enforcement of these standards.

To ensure adequate protection of the consumer, it was essential that the knowledge of these vital standards and how they should be complied with was shared as widely as possible among all involved in the manufacture, purchase, promotion and distribution of condoms.

The *WHO Specification and Guidelines for Condom Procurement* was first written in the late 1980s and has since been periodically updated to provide the latest information both on the capability of the condom industry to manufacture quality condoms and on the quality assurance procedure WHO has established for the purchasing of high quality condoms.

The document was designed to provide a set of purchase specifications that ensured the highest level of safety consistent with high volume purchases, the needs of different population groups, harsh environmental conditions and the probability of less than ideal conditions of storage and distribution.

In the last 10 years, the need to promote the condom as a barrier against the spread of HIV has led to considerable advances in the technology used to manufacture condoms and has created more awareness of the importance of establishing systems of quality assurance. Furthermore, research has given us new insights into the relationships between laboratory tests on condom ageing, ways to protect condoms from deterioration, and the human experience they are designed to simulate.

WHO, in coordination with the Joint United Nations Programme on HIV/AIDS (UNAIDS), held a three-day meeting of a Technical Working Group in Geneva in November 1997, bringing together representatives

of condom manufacturers, donor agencies, research institutes, testing laboratories, international and nongovernmental agencies, and procurement agencies, as well as technical experts and national programme managers. The purpose of the meeting was to review the document *Specification and Guidelines for Condom Procurement* and to propose changes and improvements on the basis of a review of the latest evidence or principles of best practice.

The outcome of the meeting was a series of recommendations on issues related to the effective performance of condoms, the comfort and confidence of the user, and the health and safety of the population at large.

This document has benefited from considerable updating and incorporates the majority of the recommendations made at the meeting. Some indication of future refinements will be found within its pages, and these items foreshadow WHO's continuing policy of reporting technological developments by manufacturers and the latest research findings which advance the frontiers of protection for the consumer.

Section 1

Guidelines for Condom Procurement



Photo: UNFPA

Guidelines for Condom Procurement

1 Introduction

1.1 WHO Specification and Guidelines for Condom Procurement

The *WHO Specification and Guidelines for Condom Procurement* focuses primarily on procurement issues related to condom quality since these procedures differ significantly from those used to procure other health care products.

The purchaser must first provide a specification that details the characteristics and quality of the product to be manufactured. The purchaser must then verify that the product conforms to the specification before purchasing the product.

These precautions are necessary because:

- the condom manufacturing industry was established many years before the introduction of medical device regulations and has only recently been brought under the scrutiny of regulatory agencies;
- poor quality condoms fail to provide adequate protection;
- condom promotion programmes lose credibility if they use poor quality condoms;
- condoms can degrade quickly in tropical conditions unless they are appropriately formulated and packaged.

The quality assurance process incorporated into the procurement procedure is designed to protect both the procuring agency and the consumer since there may be substantial differences in the quality of the condoms produced by different manufacturers.

Always specify the quality of the product and verify the quality of the product before it is purchased.

The *WHO Specification and Guidelines for Condom Procurement* has been divided into 2 sections.

Section 1 of this document has been designed to provide a step-by-step guide to the procurement process and describes the different quality assurance measures that are applied to ensure the procurement and distribution of high quality condoms.

Section 2 details the essential components of a good specification for condoms suitable for use in developing countries and tropical environments. It defines the *general* and *performance requirements* which address the fundamental aspects of safety and efficacy and should not be changed. It also details the *design requirements* which may be changed within reasonable limits to meet the special needs of users and programmes.

The *WHO Specification* is not intended to be a universal prescription for condoms in all programmes and all circumstances of use. While the use of the *WHO Specification* exactly as in this document will provide condoms suitable for many situations, programme managers should consciously review the design requirements to ensure they are appropriate for the programme's specific needs.

The *WHO Specification* guides this decision-making process and should be adapted to the purchaser's own established purchasing procedures and requirements. This document reflects the *WHO Specification*, which has been successfully used in many large procurement programmes.

1.2 Who is this document intended for?

This document is intended primarily for managers and their procurement officers working in reproductive health care programmes,

particularly family planning and STD/AIDS prevention programmes, who have the responsibility of supplying natural latex male condoms to their target population.

Bulk procurement agencies, manufacturers and test laboratories will also need to study this document in preparation for the supply of condoms and quality management services to programmes using the *WHO Specification*.

In addition to these primary users, the document will be useful to national regulatory agencies, standards bodies, social marketing programmes and public health policy-makers as they work to improve the availability, acceptability and effectiveness of condoms in their target populations.

1.3 Addressing needs of developing countries

With a few exceptions, the scientific basis for establishing standards of production for condoms has in the past been dominated by developed countries and the condoms available were styled to the needs and demands of those markets. The quality requirements placed emphasis on freedom from holes, and the strength and elasticity of the latex film. The WHO initiative, while not dismissing these attributes, widened the emphasis to provide for situations in which economic and social circumstances dictated a limited choice of products and the need for:

- adequate protection against harsh environmental conditions;
- appropriate length and strength of the whole condom in relation to effectiveness, comfort and size;
- appropriate levels and type of lubrication;

- appropriate information on how to use condoms;
- allowance for inadequate systems of storage and distribution.

The *WHO Specification* contained in this document gives special attention to the need for overall product strength and elasticity to provide comfortable fit and resist breakage, and the ability to withstand long periods of storage in tropical climates without significant deterioration.

1.4 Difference between a specification and a standard

The distinction between a *specification* and a *standard* confuses many people; in fact, some believe them to be the same thing. This is understandable, because both specifications and standards deal largely with the same attributes.

1.4.1 Standards

Standards are normally developed by voluntary standards bodies in collaboration with manufacturers and consumer groups. In some cases, they may be prepared by regulatory authorities. Safety and efficacy standards are published by national or international regulatory authorities or standards bodies to establish a minimum level of quality for products (e.g. condoms) that are made or imported, and sold, within a particular country or region. The principal international standards authority is the International Organization for Standardization (ISO), a worldwide federation of national standards bodies responsible for drafting international standards for

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manufactured products based on the best available evidence.

A standard is concerned primarily with safety and security, usually covers only essential performance attributes and should not be compromised. A standard is concerned not with the special requirements of individual buyers but with the quality of the product that is produced.

Design features that are a matter of choice and discretion (e.g. colour) will not normally figure in a standard (except perhaps to stipulate that any pigment used must be non-toxic and non-irritant). Standards also provide consensus on the procedures and protocols to use when carrying out basic tests for quality verification.

A standard establishes a minimum level of quality that can ensure the safety and efficacy of the product.

A specification is a statement of the buyer's requirement and will cover all attributes of the product.

1.4.2 Specification

A specification, on the other hand, is a statement of a buyer's requirements and will cover all attributes and features of the product – the essential, general and performance requirements and the discretionary design requirements.

In some cases, the specification may demand a higher level of quality than a national standard requires, as well as additional features. By way of example, the current ISO standard has no package integrity requirement. The *WHO Specification*, by contrast, sets package integrity requirements for condoms because

they have to withstand tropical or other harsh conditions of storage and distribution.

A specification may contain within it some or all of a standard as its essential performance requirement. The specifications contained within these WHO guidelines are based when appropriate upon ISO 4074 Standard for Latex Rubber Condoms.

The *WHO Specification*, and most condom standards, exist principally to protect the consumer.



Guidelines for Condom Procurement

2 Essential Components of Quality Assurance

2.1 Quality management

To achieve high quality, condoms must be well designed and formulated, and carefully made. To maintain that quality until the condom is supplied to the user, storage and distribution systems need to be effective. Both the manufacturer and the large volume purchaser should develop and maintain a quality management programme to establish the procedures, structures and record-keeping necessary for effective and sustainable quality management. Standards and guidelines for quality management have been issued by standards bodies and regulatory agencies in several countries. A well designed factory and product, together with an effective top-down quality management system, form the foundation for consistent quality in the long term.

2.2 International Organization for Standardization (ISO)

The ISO has created a number of model standards for quality management. Perhaps the best known is the internationally recognized ISO 9000 series of standards, which prescribes in great detail the documentation, procedures and structures to be followed in factories to facilitate the production of a consistent standard in the output of services and products.

The systems of quality management, generally known as “Good Manufacturing Practice” (GMP) can be used by most factories regardless of the product and are audited by regulatory bodies. Other ISO quality management guidelines are ISO 13485 and ISO 13488. These are intended to be versions of ISO 9001 and ISO 9002 applied specifically to medical devices. Europe uses EN 46001 and EN 46002, which are very similar to ISO 13485 and 13488. The US uses its own code of GMP, with slightly different emphasis from the ISO requirements.

WHO suggests that purchasers should not rely unduly on certification of GMP to ensure that condoms supplied are of high quality and meet the required specification. The proof of technical competence also involves evidence of appropriate design and the verification of consistent compliance with performance requirements of standards and specifications.

The international basis for condom standards is provided by ISO 4074 (latex rubber condoms). This document is drafted by a technical committee (ISO/TC/157) and is currently under extensive revision. Many of the product tests prescribed by WHO are derived from ISO 4074.

Readers of this WHO document will see references to ISO 2859. This document is issued by ISO and gives sampling plans and accept/reject criteria used to determine whether particular lots of a product conform to maximum acceptable levels of quality. ISO 2859 provides tables that enable the user to choose a sample size appropriate to the size of the lot of articles and the importance of the attribute being tested. WHO uses ISO 2859 for determining sample sizes in most of the tests in the *WHO Specification*.

2.3 National regulatory authorities

National regulatory authorities, such as the United States Food and Drug Administration (USFDA) and other key agencies control GMP and end-product condom standards in many developed countries.

The Medical Device Directive, adopted by EU Members and Switzerland, requires conformance with the European CEN standard for condoms, and with EN 46001 or 46002 from June 1998. Compliance with the European requirements at the factory level is assessed by a series of notified bodies, appointed by each member nation.

Regulatory agencies license drugs and medical devices for use in the country or region, carry out audits and test products. They may adopt standards issued by standards authorities and make them mandatory. They generally have the authority to recall products and close factories in the event of continued non-compliance with their regulations.

Drug controllers, AIDS prevention authorities and Ministries of Health are beginning to take on a similar role in developing countries. A number of these authorities have based their standards on the WHO Specification, and several are actively participating in the drafting of the new ISO condom standard.

National regulatory authorities issue standards, carry out audits, test products, have the authority to recall products and, with continued non-compliance, close factories.

2.4 Voluntary standards

In many countries, industry, government and consumer bodies cooperate to produce standards for various products, including condoms. These bodies generally work to develop a consensus and have been instrumental in the development and validation of new test methods. They are an appropriate forum for discussing common concerns at national level. National standards bodies may belong to the ISO, which is responsible for developing the international condom standard (ISO 4074). The oldest and best-known national condom standards are those of Sweden, the USA and the United Kingdom.

The national standards authorities are responsible for nominating delegates to represent them at the ISO technical committee meetings that

draft ISO 4074. It is expected that national standards bodies who participate in the preparation of an international standard will adopt that international standard as far as is practicable within their country.

2.5 The role of test laboratories

Third party test laboratories have an important role in providing objective testing of condoms, both for the pre-qualification of suppliers and for lot-by-lot compliance testing prior to delivery. Some laboratories provide other quality management services, including diagnosis of quality problems, GMP training and review and inter-laboratory comparison of test equipment, procedures, and stability trials.

Other organizations provide independent sampling services, travelling to the manufacturer's factory or warehouse to take random samples for testing.

In choosing a testing laboratory, purchasers should give due weight to whether or not a candidate laboratory participates in voluntary inter-laboratory trials.

Inter-laboratory comparison of condom test laboratories is an important service that has come into existence in recent years. It helps to ensure that the measurements made by the manufacturer, regulatory authority and test laboratory are compatible, and contributes to avoiding disputes due to measurement differences or errors. The laboratory should also be part of an internationally recognized laboratory accreditation scheme. This scheme is comparable to the GMP certification offered according to ISO 9000, with the additional requirement of a technical review by an experienced technical auditor of the competence of the laboratory staff and the efficacy of the equipment and procedures.

Testing laboratories provide objective testing of condoms and other quality management services.

Testing laboratories should participate in the voluntary inter-laboratory trials and be part of an internationally recognized laboratory accreditation scheme.

2.6 Collaboration for quality products

Once an agreement with a supplier is signed, both the purchaser and the supplier have a common interest in having the product delivered in a timely manner. While the purchaser and the testing laboratory need to maintain their independence and objectivity, good communication among all parties facilitates the resolution of any problems that may arise.

For example, if the test laboratory finds a problem with a shipment of condoms, it should be discussed immediately with the factory in order to minimize the production of any further condoms with similar problems.

If such information is filtered or delayed, the manufacturers' costs will rise and supply of acceptable products to the user will be delayed. Similarly, the laboratory can give assistance to the purchaser in interpreting results, particularly when the condoms are of marginal quality.

2.7 Selection of suppliers

The selection of the right supplier is a matter of critical importance to the success of the programme. This is because a supplier who fails

to deliver consistently good quality condoms on time causes disruption and lasting damage to the programme.

Condom procurement is not like procurement of other health care products, because the manufacturers who make up the condom industry vary widely in their capability to produce high quality condoms on a continuous basis. WHO and UNFPA have successfully bought condoms over many years from factories chosen by pre-qualification, competitive tendering, and compliance testing by an accredited testing laboratory of each lot of condoms purchased. Companies that were able to meet the requirements on a continuing basis did so as a result of their appropriate condom formulations and designs and their high standards of quality management.

2.8 Tendering

The selection of a supplier is generally done by tender and, all things being equal, the supplier offering the lowest price for good quality condoms will be awarded the contract. However, choosing on the basis of price alone exposes the programme to the risk of being let down by an unreliable supplier. This unreliability may show itself in the form of late deliveries or even no deliveries at all, or in offering lots of poor quality condoms that have to be rejected by the purchaser. Any of these problems can cause interruption of supplies to the consumer, leading to loss of confidence in the product and general disruption of the programme logistics.

The supplier should be selected on the basis of cost, quality of the product and the capacity to deliver in a timely fashion.

2.9 Pre-qualification – screening the capability of the manufacturer

Pre-qualification minimizes the risk of purchasing a poor quality product by screening the capability of potential suppliers, so that only those suppliers who can demonstrate they have the capacity to produce a quality product in a timely fashion will be eligible for the award of a contract, irrespective of the price tendered.

Pre-qualification is a procedure designed to test the ability of the manufacturer to produce homogeneous lots of condoms of good quality on a continuing basis, and to exclude before or during the tendering process those who cannot.

There are a number of different approaches that can be adopted to undertake the pre-qualification of suppliers and the approach used will depend on the quantity of the product that is required and the frequency of the order.

Purchasers who place large and frequent orders for condoms frequently carry out pre-qualification in advance of any tender. This generates a list of qualified manufacturers who are invited to tender for an order whenever an order is to be placed. This method is also useful in situations where purchasers must wait for funds from donors before they can place an order.

Where orders are placed less frequently, say once a year or less, pre-qualification can be combined with the tendering procedure. This method of screening the suppliers in parallel with conducting the tender ensures that only suppliers who can demonstrate their capability will be eligible for award of contract,

irrespective of the price tendered. This system is designed to minimize the expense and complexity of undertaking the pre-qualification procedure with a large number of suppliers, while providing adequate screening of a short list of bidders whose bids appear to have a reasonable prospect of success on the criterion of price.

The method of pre-qualification described in this document can be used for either approach but, in order to assist the smaller purchaser in developing a procurement procedure, the combined system of pre-qualification and tendering is described in Chapter 3.

The three steps in the pre-qualification procedure are:

- examination of documentary evidence presented by the supplier;
- testing of condoms manufactured by the supplier;
- when appropriate, factory inspection undertaken by a trained quality management specialist.

In the case of small quantity requirements, factory inspection may not be warranted. Factory inspection is generally undertaken when there is inadequate documentation of the factory's quality assurance programmes.

In some cases, financial supervisory bodies discourage the use of pre-qualification because they fear it may compromise the impartiality and transparency of the tendering process. These fears stem from a lack of awareness of the large variations in condom production quality in the industry. In fact, these concerns are needless, because *pre-qualification simply introduces a capability and quality*

screening element, additional to the price screening, in order to make supplier selection better informed and more successful.

Suppliers with a recent successful track record of supplying condoms that conform to the *WHO Specification* need not be put through the full pre-qualification process. Verification of their previous performance (e.g. using the aggregate analysis detailed in section 2.11 plus documentary evidence) should be sufficient.

The purpose of pre-qualification is to:

- minimize the risk of delays to the programme from rejected lots; (Note that the words *lot* and *batch* are synonymous. In this document, as in ISO 4074, *lot* is used.);
- minimize the indirect costs that occur when replacement lots must be made;
- ensure that the supplier concerned has the physical capacity to make the goods according to the delivery schedule;
- maximize the likelihood that the product quality will be consistent throughout the order;
- verify that the supplier has a quality control and management system that controls those properties and parameters that cannot practically be checked on the finished product, such as documentation provided with a bid, certification of GMP and compliance with regulatory standards, etc.

Pre-qualification is a procedure designed to minimize risks and maximize the probability that a quality product will be purchased.

Pre-qualification will not guarantee that the condoms will always be of the highest quality or will always arrive on time. However, it will go a long way towards eliminating the least competent and least reliable suppliers. It is not a substitute for testing finished products before accepting them.

2.10 Compliance testing

Every lot of condoms made by the manufacturer for the contract must be tested for compliance with the specification before the purchaser accepts it. The procedure for doing this is explained in Chapters 3 and 5.

Many major procurement organizations purchasing condoms in the global market consider that lot-by-lot testing must be a permanent feature of their procedures to reduce the likelihood of purchasing defective condoms that do not comply with the specification.

WHO recommends comprehensive lot-by-lot compliance testing to reduce to the minimum the likelihood of defective condoms being purchased and distributed to the consumer.

2.11 Aggregate analysis

The sampling and testing rules permit a certain number of non-compliers in most of the tests, and these are set at levels that make it unlikely that a good lot will fail the test. The test results can, however, be borderline, and if there is concern regarding what could be considered marginal quality of successive lots of condoms a double-check has been designed to assess the

cumulative quality of each shipment or order. This is called an aggregate analysis.

The aggregate analysis provides a method for assessing quality across a number of delivered lots. All the lots of a shipment are added together to form a large lot. All the samples which have been taken, regardless of whether they have passed or failed from these lots, are added together to form a large sample. A mathematical formula is then applied to work out whether or not the shipment complies or does not comply with the specification.

In the following formulae:

D = the acceptance number for the respective acceptable quality levels (AQLs) prescribed in the WHO Specification (i.e. the permitted number of non-conforming condoms in the total sample).

N = the total number of condoms tested in the shipment for each test requirement.

Requirement

for 0.25% AQL: $D = 0.01 (0.25 N + 8 N^{0.55})$

for 1.0% AQL: $D = 0.01 (1.0 N + 17 N^{0.55})$

for 2.5% AQL: $D = 0.01 (2.5 N + 30 N^{0.55})$

for 4.0% AQL: $D = 0.01 (4.0 N + 36 N^{0.55})$

for 0% AQL: $D = 0$

Action

If the total number of non-conformers in the aggregated lots for the individual test is greater than D, then the collective lots are of a marginal quality.

If this non-compliance is repeated or persistent, the problem should be discussed with the supplier. Unless it can be rectified quickly, consideration should be given to removing the supplier from the buyer's list of pre-qualified suppliers

Note: Aggregate analysis is used to assess marginal quality. It cannot be used to reject lots that have previously been accepted under the lot-by-lot compliance tests.

Aggregate analysis as defined here is used to determine whether a series of lots which have been individually accepted are collectively meeting the AQL.

Aggregate analysis is used in the pre-qualification of supplies.

Guidelines for Condom Procurement

3 Essential Steps in Condom Procurement

3.1 Four methods that can be used to purchase condoms

- *Buy condoms from an international organization which already purchases them in large quantities*

Both WHO and UNFPA buy condoms using the *WHO Specification*, and undertake both the pre-qualification of manufacturers and lot-by-lot compliance testing for every order that is placed. The packaging for these condoms is in plain foil with no consumer packs. There is a revolving stock, so supply is available at short notice.

This option is ideal for organizations needing only a moderate quantity of condoms, without special design or packing requirements. It should be remembered that condoms can be packed by the purchaser into consumer packs to provide product identity.

If the purchaser requires a more distinctive pack or a modified design of condom, it may be possible with advance notice for one of these organizations to arrange for their manufacture as part of a larger order.

- *Use a third-party purchasing agent*

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 would be responsible for handling the pre-qualification of potential suppliers, selecting the supplier, arranging compliance testing and shipping.

- *Buy directly from a condom manufacturer by competitive bidding*

In this case, the purchaser must develop the specification, undertake the tendering and pre-qualification of potential suppliers, select the manufacturer, arrange for compliance testing and shipping.

- *Buy directly from a condom manufacturer on the basis of an ongoing long-term relationship*

While this arrangement would begin in the same way as the one above, it relies on the continuing purchase from one manufacturer of a large quantity of condoms over a period of at least a year. The method works best where the order is large enough to use the whole output of one production line on a continuing basis.

If a supplier performs well over an initial period, and local procurement rules allow, a performance-based renewable purchase agreement may offer the most cost-effective and low risk approach to ensuring condom quality.

Using this approach, a performance goal is set (e.g. lower variance on lubrication quantities or maintenance of a certain process average for inflation volume) which, if achieved by the supplier in addition to overall good performance, leads to an extension of the purchase agreement.

WHO does not recommend buying condoms from a commercial distributor or agent since such condoms are usually not traceable to their manufacturer, and quality issues are thus more difficult to address.

3.2 Preparation of documents to procure condoms

- *Formulate the condom specification (an example of a specification is provided in Section 2 of this document).*
- *Decide on the pack design.*
 - Special package markings and consumer cartons may be needed in social marketing programmes.
- *Be sure you are familiar with the relevant parts of your country's standards and regulations on condoms, as well as import regulations and procedures. This will facilitate rapid clearance on receipt of the product and ensure compliance with local requirements.*
- *Decide on the procedure and estimate the cost for pre-qualification.*
- *Design a contract that stipulates at least these key points:*
 - the condom specification including the tests for general, performance and design requirements;
 - the design and packing of the condoms (using the *WHO Specification* or an accepted variant);
 - the delivery schedule and statement of shipping arrangements;
 - the compliance testing procedure;
 - resolution of disputes.
- *Ensure that the results of the testing laboratory chosen for the pre-qualification and compliance testing will be accepted by the manufacturer.*
- *Select a supplier on the basis of capacity to supply the product, the quality of the product, and price.*

3.3 Procurement procedures

3.3.1 Invitation to bid

An invitation to bid should be circulated as widely as possible among potential suppliers.

This invitation should call for expressions of interest and should include a copy of the purchaser's specification and details of the requirements (quantities and timing of delivery).

Suppliers may be located using one or more of the following:

- lists of known suppliers (such as lists provided on request by WHO);
- referral by other purchasers;
- advertisements in suitable media.

The letter or advertisement will invite suppliers to apply for a set of bidding documents which will include instructions to bidders, the purchaser's specification, a draft of the supply contract, and forms on which to submit bids. At the same time manufacturers will be asked to confirm that they:

- are interested in supplying on a continuous or occasional basis;
- are capable of providing the quantities required within the desired time frame;
- have a proven record of manufacture of products that conform to the WHO Specification, the buyer'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 a charge to cover the cost of sampling and testing for pre-qualification.

WHO does NOT maintain a list of pre-qualified suppliers.

Experience has shown that manufacturers' quality systems and product quality may vary over time and WHO could not guarantee the accuracy of such a list.

WHO conducts a pre-qualification process before each new contract is issued.

WHO will supply a list of potential suppliers and testing laboratories on request.

3.3.2 Bidding procedure

In response to the supplier's request, the purchaser sends out a set of bidding documents. Some purchasers charge a nominal fee for supplying these documents, with the object of discouraging people who do not have the ability to supply from asking for the documents out of curiosity.

The bidding documents will include instructions for bidding, a specimen contract, the specification, and bidding forms on which the supplier submits the bid and certifies that the products conform to requirements. The reason for using a formal bid form is that it will become part of a contract if the bid is ultimately successful.

3.4 Assessing the capability of potential suppliers

3.4.1 Documentation

With the bid, suppliers should be asked to provide the following documentary information:

- evidence that they are a primary manufacturer (i.e. they do formulation, dipping, testing and packaging of condoms on their own premises);
- production history, products currently manufactured;
- at least two institutional customer references, with addresses, e-mail, fax and telephone numbers;
- capacity of the factory and available capacity for this order;
- regulatory compliance credentials and applicable national regulatory code;
- other GMP and quality management certifications;
- data to support claimed shelf-life at tropical temperatures (e.g. ageing studies at 35°C for the claimed shelf-life);
- any available information on toxicity, allergenicity, and anti-oxidants;
- statement of ability to comply with the specification attached (this statement may be incorporated into the bid form);
- explanation of the manufacturer's codes and markings.

The purchaser should also seek information on the potential supplier's financial situation to establish that there is adequate working capital available to ensure the timely supply of high quality raw materials, and that all necessary maintenance can be carried out.

3.4.2 Evaluating bids to prepare a short list of suppliers

The bids are evaluated on the basis of the two bid components:

- documentation;
- price.

From the prices tendered and the responses to the enquiries a short list of the lowest bids can

be drawn up. At this stage, suppliers who are not manufacturers (dippers) should be eliminated except for very small orders. Some degree of flexibility can be considered for other items (e.g. if a factory has ISO 9000 certification or CE marking, and no history of supplying institutional purchasers, or vice versa).

Any number of suppliers can be included in the short list at the discretion of the purchaser.

3.5 Pre-qualification

When the short list is compiled, pre-qualification of suppliers is carried out. Instructions are given to a sampling agency to draw random samples of 900 condoms from each of three lots at each manufacturer on the list.

These lots should be no more than 60 days old and should be sent by airfreight or courier within 24 hours to the testing laboratory chosen by the buyer.

A single laboratory should be used for testing the samples from all suppliers. The samples should be tested for the following requirements described in Section 2, using single inspection, and assuming a lot size of 150,001-500,000.

Test for:

- resistance to oxidation;
- bursting volume and bursting pressure;
- bursting pressure and volume after ageing at 70° C / 7 days;
- freedom from holes;
- package integrity.

- It is important to recognize that stocks drawn at random from a manufacturer may not comply with all requirements of the *WHO Specification*.

- The manufacturer will be producing for existing clients with their own requirements. Therefore the manufacturer must be asked to indicate the specifications to which the products have been produced.
- The inflation and freedom from holes requirements must be complied with.
- At the time of sampling, the manufacturer may be given the opportunity to exclude a small proportion of stock from sampling if that stock was produced for markets where ISO 4074 does not apply.
- Condoms should have a minimum shelf-life of three years.

From the results of these tests, the supplier whose samples meet all the test requirements, tenders a reasonable price and provides the most valid documentation is judged to be the successful bidder, and would be awarded the contract.

Award the contract to the supplier on the basis of all samples meeting the test, requirements, price and validity of documentation.

3.5.1 Factory inspection

In some cases, particularly for large contracts, it may be desirable that the supplier's facilities are inspected. For small contracts a factory visit would be neither practicable nor cost-effective. By undertaking such a visit, the buyer can gain additional insight into the factory quality management programme and capability and can verify, as far as is possible, the information given in the written responses. This inspection should

be undertaken by a person familiar with the condom industry who has experience in carrying out such inspections.

Important note:

Pre-qualification of prospective suppliers is an important precaution to ensure that the proposed suppliers have the resources and capability to satisfy the buyer's requirements.

Pre-qualification, if properly conducted, can save a great deal of time and expense when dealing with orders and deliveries later on.

Pre-qualification does not generally reduce the need for pre-delivery compliance testing, which should in most circumstances be carried out in accordance with the protocols outlined in 3.6.

3.6 Sampling and compliance testing

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

It is a fact, however, that even the most careful and conscientious manufacturer can sometimes suffer quality lapses, possibly due to climate changes, variations in raw material characteristics, or even temporary malfunction of process control systems. For this reason it is important to verify that every lot complies with the requirements of the specification before it is accepted for shipment to the purchaser.

After an extended and unbroken period of continuous compliance by a supplier, a purchaser may decide to test only a portion of the

consignments offered. However, constant vigilance is needed and a return to testing every lot must follow the slightest lapse in quality performance.

When a consignment (or a manageable

WHO recommends that every lot be tested for compliance with the *Specification* before it is accepted for shipment to the purchaser.

portion of a consignment or order) is complete and ready for shipment, the supplier will inform the purchaser that the consignment is ready for testing.

The purchaser then instructs a sampling agency to visit the supplier's factory to draw samples from the lots that have been produced for the order, in accordance with sampling guidelines provided in ISO 2859-1 (Table 1 on page 30 gives the sample sizes and acceptance limits for the most common form of sampling – single sampling normal inspection).

The sampling agency sends the samples direct to the testing laboratory chosen by the purchaser, where they are subjected to the quality tests detailed in Chapter 5 and the *WHO Specification*, Section 2. A number of laboratories are highly experienced and qualified to undertake condom testing.

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, then 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 *Appendix I*.

The use of the options in *Appendix I* requires expert advice, which should be sought from an experienced testing laboratory or quality control expert. In all cases the supplier should supply the results of the production line and pre-release testing for each lot, preferably in the form of control charts.

There is no obligation for the purchaser to pay for failed lots. There are, however, certain circumstances in which it may be in the buyer's interest to accept them, and these are described in Chapter 4.

3.7 Dividing the tender into separate orders

Where the contract is for a large quantity (say 50 million or more) it may be prudent to divide it into more than one order. There are two principal reasons for doing this:

- There are several small manufacturers who are capable of delivering high quality condoms, but whose available capacity might prevent them from bidding for the whole of a large annual contract. Splitting the total into more than one lot gives the purchaser the opportunity to use smaller, quality companies.
- If one of the suppliers were to run into production or quality difficulties, this need not result in a complete cessation of supply, because the other supplier would be able to continue to supply.

If the tender is to be divided into multiple orders, each order will be treated as a separate tender process and contract. Suppliers should be permitted to bid separately for one or both (all) orders.

Guidelines for Condom Procurement

4 What to do if Condoms Fail to Comply

4.1 Options for dealing with failed lots

If a lot fails any of the tests in the WHO Specification, the protection of the consumer must be paramount in deciding what action to take.

- In the case of failure of a *performance requirement*, the lot should be rejected. There should be no exceptions to this rule.
- If a lot fails to meet a *design requirement*, the remedial action taken will depend on the degree of non-compliance, the persistence with which the manufacturer has failed to meet the specification, and the impact that non-acceptance would have on the flow of condoms to the programme.

In the case of minor failures of design requirements (e.g. a relatively small excess of lubricant, or a couple of millimetres short on length) it may well be in the interests of the purchaser (and, incidentally, in the interests of the consumers) to accept such lots, rather than suffer an interruption in supply.

In many cases, it will be sufficient to bring the design non-compliance to the attention of the supplier, and to request that the compliance procedures within the factory be examined and tightened up. A warning that persistent non-compliance in the future will lead to lots being rejected will usually be sufficient to remedy the situation.

4.2 Resolving disputes

If a lot is rejected, the manufacturer may dispute the results of the laboratory test. The available history of the manufacturer's production for the client should be examined using the aggregate analysis described in Chapter 2.11, including both accepted and rejected lots. The analysis should calculate both the pass and the fail criteria and the process average over as many lots as possible.

In general, requests for re-tests should be treated with caution, as the ISO 2859 acceptance criteria already gives the manufacturer a 95-99% chance of having a marginal lot accepted.

The manufacturer and purchaser must accept that there will be statistical errors, and that these are most likely to occur when the quality of the product is marginal.

If the aggregate analysis does not comply on the pass/fail criteria, no re-testing should be considered under any circumstances. Other-wise, a re-test can be considered. If only a few lots (say, up to three) are available, the decision must be made subjectively.

If a re-test is agreed, a supplemental sample will be taken which, when added to the original one, will produce an enlarged sample corresponding to Code Letter P (800 condoms) for the air-burst test, and Code Letter Q (1250 samples) for the test for holes. The test results of the supplemental sample are added to the existing results and the lot is then assessed on the combined result. The testing laboratory can advise on this re-test procedure.

Financial responsibility for re-tests needs to be considered at the time of writing the contract.



Photo: London International Group

Testing Condoms

Guidelines for Condom Procurement

5 Principles of Condom Testing

5.1 Random sampling

In the great majority of cases, the *WHO Specification* stipulates that testing of a proposed shipment shall be carried out on randomly selected samples from that shipment. The size of each sample is calculated by reference to ISO 2859-1. This is the simplest and most widely used sampling scheme for checking multiple lots, using attributes criteria (that is checking whether a product has a defect or not).

The rationale is as follows: statisticians have determined that if you test a sample drawn randomly across a lot, the test results from the sample will reflect the actual condition of the whole lot, subject to a certain margin for error. The larger the sample, the less the margin of error. (Obviously, if you tested every single condom in the lot, then your result would be absolutely accurate, but you would of course have destroyed the lot in testing!)

ISO 2859-1 defines a number of general sampling levels: G-1, G-2, G-3. The higher the number, the larger the sample, and the greater the accuracy. There is also a series of special sampling levels: S-1, S-2, S-3 and S-4. The special levels operate below the general levels, so S-4 is a lower level of sampling than G-1.

In ISO 4074, which deals specifically with condom standards and testing, the sampling level for each test is stated. The *WHO Specification* does the same. In general, the more critical the test, the higher the sampling level. That is why, for example, critical specifications like burst volume or leakage are sampled at the G-1 level, whereas less sensitive features such as length are sampled at S-2.

The sample sizes at any level are not a constant percentage of the lot. The larger the lot,

the smaller, proportionally, is the sample. To arrive at the number of condoms to be sampled from a particular lot at a given level, the sampling agency refers to the tables in ISO 2859-1.

5.2 Acceptable quality level (AQL) and acceptance number

WHO recognizes that current technology does not enable manufacturers to produce condoms that are completely free from defects.

For that reason, a small percentage of defects - the AQL - are tolerated. WHO regards this AQL as an upper limit for the percentage of defects, not as a target average. *It expects that manufacturers will have a defect rate comfortably below the AQL most of the time.*

For each attribute an AQL is designated as the maximum percentage of non-conforming condoms in the lot that will be accepted most of the time by the sampling scheme. AQL is described in ISO 2059-1 as follows: "when a continuous series of lots is considered, the quality level which for purposes of sampling inspection is the limit of a satisfactory process average". For example, WHO specifies an AQL for freedom from holes of 0.25. This means that in the longer term the maximum acceptable proportion of condoms with holes is 0.25%.

Compliance with an AQL is assessed by testing a sample from the lot. Clearly, the percentage of non-conforming condoms within this sample may differ from that in the lot because of the random nature of the selection process. For this reason an acceptance number is defined which allows for this statistical variability and ensures that the manufacturer is treated fairly.

The acceptance number is higher than the number of non-conforming condoms that might be expected in the sample as estimated by

multiplying the sample size by the AQL. Acceptance numbers are determined by reference to the appropriate table in ISO 2859-1 for a given sampling plan and AQL.

WHO expects that manufacturing and quality control techniques will improve with time and that the limits and AQLs quoted in this specification will be revised accordingly. More stringent requirements may apply in future editions of the *WHO Specification*.

Table 1 Sampling and acceptance table, single sampling – normal inspection.
Example of a sampling scheme (for full details refer to ISO 2859-1).

Requirement	AQL %	Inspection Level	Lot size					
			35,001 - 150,000			150,001 - 500,000		
			Defects			Defects		
			Sample	Accept	Reject	Sample	Accept	Reject
Burst volume and pressure	1.0	G1	200	5	6	315	7	8
Burst after ageing	-		80	MEAN		80	MEAN	
Freedom from holes	0.25	G1*	315	2	3	315	2	3
Package integrity	2.5	S-3	32	2	3	32	2	3
Length	1.0	S-2	13	0	1	13	0	1
Width	1.0	S-2	13	0	1	13	0	1
Thickness	1.0	S-2	13	0	1	13	0	1
Lubricant quantity	4.0	S-2	13	1	2	13	1	2
Package material and markings	2.5	S-3	32	2	3	32	2	3

* at least at code \pm level M

Source: ISO 2859-1

5.3 Testing costs

Some buyers question whether it is necessary to bear the cost of sampling and testing every lot when dealing with a supplier of whom they have experience and in whom they have built up confidence.

Some have experimented with “consignment testing”, i.e. regarding a whole shipment as a single lot. The trouble with this method is that the whole shipment is unlikely to have been made under the uniform conditions required for a lot manufactured at the same time with identical properties. (See Appendix IV for the full definition of a lot.) 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 constituent lots.

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

Since the sole purpose of the strict testing regime recommended by WHO is to protect consumers who are not in a position to check the quality themselves, the cost of testing, at around 6-10% of the cost of the condoms themselves, might be considered a relatively inexpensive method of insuring against the delivery of poor quality condoms to a programme.

It is essential that the purchaser provides for the cost of sampling and compliance testing when preparing a procurement budget.

There are, however, certain ways in which these costs can be contained, and even reduced, while still maintaining effective vigilance against defective goods being supplied.

WHO has reviewed various methods that have been proposed by buyers for reducing quality assurance costs. These are described and commented upon in Appendix I.

It should be stressed that any cost-saving regimes should be introduced only after fully proving the reliability of the supplier by an extended period of full lot-by-lot testing.

After introduction, cost-saving regimes should be used with caution, because the result of faulty condoms being used can be disastrous both for the users and for the credibility of the programme that distributes them.

Any reduction in the number of condoms tested reduces the amount and accuracy of information available about the lots being supplied to the purchaser.



Photo: London International Group

Inflated Condom

Guidelines for Condom Procurement

6 How to Prepare a Specification

The purchaser must provide to the manufacturer a detailed and unambiguous description of the required product. The specification is attached to the bidding documents and will form part of the ultimate supply contract. Many purchasers will find the *WHO Specification* in Section 2 of this document can be used unchanged (except for the specification of the pack design) to provide reliable products suitable for their programmes. The design requirements should always be reviewed to ensure that they are appropriate for the specific needs of the programme.

6.1 Components of a specification

6.1.1 General requirements

These specify the safety of constituent materials and other characteristics, such as shelf-life. These properties are difficult or expensive to test on a regular basis, and in any case should not vary from lot to lot. The manufacturer should carry out these “type” tests before introducing the product on the market and must present documentation to satisfy most of these requirements.

6.1.2 Performance requirements

These specify the essential performance attributes of the condom, which must be tested regularly since the quality of these attributes may vary due to the manufacturing process.

General and performance requirements address fundamental aspects of safety and efficacy. The requirements detailed in the *WHO Specification* should be changed only when there is evidence of compelling new research findings.

6.1.3 Design requirements

These may be changed within reasonable limits to address different programme needs, such as social marketing programmes focusing on commercial sex workers or other target groups.

Programme managers should review the design requirements in the *WHO Specification* and determine what alternative requirements might better fit their programme and target population needs.

6.1.4 Packaging requirements

The *WHO Specification* has stringent requirements for condom packaging in order to protect the condom during transportation, storage and distribution. Other packing, such as consumer packs for delivery will depend on the individual requirements of the programmes and have not been specified.

The specification lists the purchaser's various requirements and describes the means by which those requirements will be verified.

The principles involved in defining these requirements are outlined below. Details of each requirement are described in the *WHO Specification* in Section 2.

6.2 General requirements

General requirements cover the conditions under which the condoms are manufactured, as well as those qualities that should be assessed by the manufacturer before the condoms are put on the market. The tests for these latter qualities are known as “type” tests because they define the

specific type of condom and should usually remain unchanged from lot to lot.

They include:

Purity and safety of constituent materials used to make the latex rubber condom.

Safety of materials (powders and lubricants) applied to the condom.

Currently, there is insufficient evidence to incorporate specific biocompatibility requirements or tests, but this may be done in future editions of the *WHO Specification*.

WHO requires the testing laboratory to carry out a type test to determine the degree of resistance to oxidation of the condom independent of the package. Although an impermeable, hermetically sealed primary container is required by the *WHO Specification* and is essential for protection of condoms in warm environments, some packages become damaged or lose their integrity during storage. Antioxidants incorporated into the latex formulation provide a second level of protection against oxidative deterioration in the event that the package becomes damaged.

As a matter of necessity, type tests are also used where the cost of repeated testing is prohibitive.

Shelf-life and expiry date.

This edition of the specification is the first to include a requirement for shelf-life and expiry date. Eventually, a claimed shelf-life will have to be supported by real-time stability studies conducted under temperatures that represent the severest average conditions likely to be encountered during storage and distribution.

While some manufacturers already have such data, it is not yet universal, and all manufacturers are encouraged to commence real-time stability testing on their products. This involves storing several lots of condoms at 35° C over the full intended shelf-life, and periodically doing inflation tests on a suitable sub-sample. For example, 30 to 50 condoms could be tested every 6 months. In this way the rate of deterioration of physical properties can be established. Compliance with the inflation requirements for new condoms at the end of the shelf-life is also required.

As an interim measure, WHO will accept accelerated ageing tests conducted at higher temperatures for shorter times, as an indication of shelf-life. The manufacturer may present any suitable data available, plus the rationale used to infer the claimed shelf-life.

The procedures of ISO 11346 or any reasonable simplification of them can be used. Future editions of ISO 4074 will provide condom-specific methods for determining shelf-life. Until these test requirements in ISO 4074 are finalized, WHO will adopt a flexible approach to determining the acceptability of the method of extrapolation from high temperature results to 35° C.

In order to generate simple, interim, shelf-life information it is suggested that oven conditioning be done at two temperatures, 70° C and 50° C. Typically, it would be expected that the mean inflation properties do not drop by more than 25% over the stated shelf-life, and that the inflation requirements of ISO 4074 part 6 be met at the end of the shelf-life. Shelf-life would be ascertained by extrapolation from the 70° C and 50° C data. The test to ISO 4074 would be performed on condoms stored at 50° C after the period that corresponds to the shelf-life at 35° C.

6.3 Performance requirements

Because it is not possible to carry out human use trials at the time of purchase, several laboratory tests are carried out to assess the barrier properties of the package and the condom, and the ability of the condoms to resist breakage.

6.3.1 Resistance to breakage

If a condom breaks during use, it has failed completely. The user and the partner are put at risk to the same extent as if they had not used a condom. Resistance to breakage is therefore a critical quality criterion for condoms.

Because breakage in use cannot be measured directly during procurement, certain substitute laboratory tests are used to assess resistance to breakage.

The *inflation test* measures the bursting volumes and pressures of condoms. Those which do not reach prescribed minimum are considered to be non-conforming condoms. Condoms with flaws in the rubber film will generally not be able to inflate beyond the limits set.

When the latex film is being stretched, two properties characterize its response. These are:

- stress (defined as the stretching force per unit cross-sectional area of the film);
- strain (defined as the percentage elongation of the film).

The ratio of stress to strain is called the modulus (of elasticity) of the rubber. Low modulus rubbers stretch easily. They are said to be easily extensible.

Human use studies have shown that latex rubber condoms with particularly high modulus (low extensibility) break more easily. Furthermore, stability studies have shown that some types of latex rubber condoms get progressively stiffer over time, particularly in hot climates. WHO's air-burst volume requirements ensure that the condoms supplied will have high extensibility (i.e. a low modulus of elasticity). Oxidative deterioration during storage can be largely prevented through impermeable containers, but if it should occur it affects both stress and strain parameters. Changes in burst pressure provide the most sensitive indicator of oxidation.

Although the interactive effect of shape, size, lubrication and other factors are not fully understood, it has been found that there is a relationship between the volume and pressure at which the condoms break under inflation and the incidence of breakage in use.

Bursting tests have the advantage of measuring the strength and elasticity throughout most of the length of the condom (although not evenly).

By contrast, the *tensile strength test*, formerly the main test of strength, and still prescribed by some standards authorities, is not included in the *WHO Specification*. The reason is that this test measures only a small portion of the condom, usually taken from the middle of the shaft. The part near the closed end is more exposed to deterioration, as it is not rolled.

Therefore, the air-burst test has a higher probability of detecting flaws in the condom throughout its length, especially at the critical closed end.

It is recommended that the requirements for air-burst properties detailed in the *WHO Specification* be strictly adhered to.

A limited number of condoms are also required to be tested after oven conditioning at 70° C. This test is not intended to provide information about shelf-life. Rather, it is intended to be a check for major errors of formulation or vulcanization.

6.3.2 Package integrity

One mode of deterioration of condoms is oxidation of the rubber, resulting in destruction of the polymer bonds and general weakness.

Tropical temperatures, which average approximately 30-35° C throughout the year (taking into account all the daily and seasonal variations), accelerate the oxidation rate.

Research has demonstrated that, if the condom is isolated from the air by means of *impermeable, hermetically sealed foil packaging and is further protected against possible package damage by silicone lubricant and antioxidant constituents within the formulated latex, the well made condom will withstand all likely environmental extremes for many years.*

A test is carried out to ensure the integrity of the condom packs. This test provides a check to detect major flaws in the material or package seals. It does not ensure that the package is impermeable to oxygen or that the seals will remain intact for the life of the product. For these assurances, the buyer must rely on evidence of shelf-life at environmental temperatures and on certification

of compliance with the specification for impermeable, hermetically sealed primary containers.

Water vapour, ultraviolet and visible light, and ozone can all accelerate deterioration of the latex film. Thus, the condom package must be *opaque and impermeable to all of these environmental influences.*

For these reasons, the *WHO Specification* pays great attention to the nature and quality of packaging.

WHO recommends:

Type-test condoms for resistance to oxidation.

Use silicone lubrication.

Specify hermetically sealed aluminium foil packaging with a minimum thickness of 8 micrometers and layers of plastic material.

Visually inspect the required aspects of packaging to verify quality and compliance.

6.3.3 Freedom from holes

A test for holes that can cause leakage of sperm or infective material was one of the first tests to be stipulated for condoms and virtually all national and international standards prescribe such a test. The average number of holes permitted has been progressively reduced as the condom

industry has found it possible increasingly to make condoms free from holes.

The test is based on filling the condoms with water and looking for leaks. In some countries, an electric conductance test is used.

WHO has chosen the visual test because it is less sensitive to interference by lubricants, relies on direct observation and can be carried out without complex apparatus.

It is recommended that the requirements for leakage testing detailed in the *WHO Specification* are strictly adhered to.

6.4 Design requirements

Design requirements are associated with local programme requirements and have to be selected by the buyer.

They are mainly concerned with acceptability, and so they are important in the sense that they may affect whether or not consumers in the programme use the condoms regularly. The decisions about these specifications should ideally be made by reference to the consumers' preferences. However, these may not be known and research into consumer needs is not always available. Feedback of consumer complaints is sometimes of help, but in most cases the buyer will have to rely on such research and/or anecdotal evidence as is available.

A property in the specification may be varied if the chosen manufacturer has difficulty in meeting it and the property is not crucial for

the programme. For example, a variation of 1 mm in the specified width may be perfectly acceptable to conform to the size of the manufacturer's installed moulds.

6.4.1 Colour and clarity of the latex film

There is no reason why condoms should not be coloured, provided that the colour is firmly bonded to the latex and is not harmful.

Coloured condoms can be used to segment a market, such as to distinguish condoms used in free clinic programmes from those used in social marketing programmes.

Do not use transparent packaging to show the colour of the condoms, as this type of material is unsuitable for the protection of the condom in many environments.

Strips of different coloured condoms are not recommended because they require the mixing of condoms from different lots, which complicates sampling for quality assurance, as well as for tracing defects. (Note that the words *lot* and *batch* are synonymous. In this document, as in ISO 4074, lot is used.)

6.4.2 Odour and taste

Some buyers may wish to specify the inclusion of a light perfume, subject to the requirement that all materials used must be non-destructive to the latex, non-toxic and non-irritant.

Unpleasant odour may be caused by gases trapped in the package and is usually due to the presence of sulphurous chemicals or to bacterial

growth. In the former case, the smell often disappears after a few moments, but since it is most noticeable when the package is opened it may have an adverse effect on the acceptability of the product.

Although there is no objective test for unpleasant smell, the testing laboratory should be alert for any unusual odour when opening samples and should immediately report any apparent irregularity to the buyer.

A disagreement may occur when taking the matter up with the manufacturer because the smell may be transient. For these discussions, it will be useful to have retained some samples from the pre-qualification testing undertaken prior to placing the order.

In discussing the problem with the supplier, the solution to the smell problem may be improved leaching of the products after dipping and/or a more careful selection of the raw materials that comprise the formulation.

If bacterial growth is suspected, the manufacturer's procedures are in question and bio-burden tests should be carried out on the product.

If bacterial growth is suspected, bio-burden tests should be carried out on the retained sample of condoms taken at the time of pre-qualification testing.

6.4.3 Width

The choice of width of condoms is important, because it is one of the main factors in

determining whether the condom is easy to put on, stays on in use, and is comfortable to the user. (The thinness of the film in association with its modulus will also play a part.).

Condoms are made in various widths. Based on studies in Australia, Thailand and the USA, and the experience of major agencies, the wider condoms (flat width 52-55 mm) will be preferred in Australia, Africa, Europe, Latin America, the Middle East and North America, and the narrower condoms (47-51 mm) will be preferred in several Asian countries (see Appendix III). Other widths are also made for small specialized markets.

The dimensions of the condom must conform to the intended population of users. There are considerable variations between individuals and there is generally no orderly market of different sized condoms even in developed countries.

WHO specifies a width of 49 mm or 53 mm with a tolerance of ± 2 for individual condoms and ± 1 for the average of the lot.

Generally, individual manufacturers will have only a limited range of sizes of formers on which they make condoms. While they can have special formers made, this will add to the cost, especially for smaller orders. It is unlikely that a width difference of 1 mm is sufficient to make big differences in acceptability.

For example, if the specified width of a condom is 53 mm then individual condoms of 51-55 mm will pass and the average lot width must fall within 52-54 mm.

6.4.4 Length

Ideally the condom should cover the entire length of the penis to minimize the risk of slippage.

Condom length is less critical than width. The length chosen by WHO (180 mm or 170 mm) is satisfactory for many users. If condoms are too short, there is a risk that they will fall off. If they are too long, the rolled up part may feel uncomfortable in use. Narrower condoms can be slightly shorter than the wider 53 mm ones. A minimum length of 170 mm has been found satisfactory for the narrower 49 mm width condom.

Minimum condom length chosen by WHO is 180 mm for its 53 mm width condoms and 170 mm for 49 mm width condoms.

6.4.5 Thickness

In recent years, condom manufacturers have learned how to make condoms thinner without increasing the incidence of holes. However, all else being equal, a thinner condom will break with less force.

The *WHO Specification* avoids the so-called “ultra-thin” condoms because of the serious consequences of breakage for family planning and STD/HIV prevention programmes. Condoms supplied under the *WHO Specification* have tended to be towards the upper end of the permitted thickness range since thicker condoms are believed to offer greater strength and protection against breakage. At some point, however, the thickness becomes an obstacle to stretchiness, and the user may complain of discomfort or loss of sensation. In recent years, thicker condoms have been

marketed under the label “extra strong”. These thicker products may have appropriate applications in some markets but are not suitable for general application in public programmes or diverse populations

For some target populations, thinner or thicker condoms may be desirable and the specification can be altered to reflect this need. The performance requirements, however, should not be altered or compromised.

6.4.6 Quantity of dressing materials (lubricant and powder)

The majority of condoms now produced in the world are lubricated. Silicone fluid is the most frequently recommended and most widely used lubricant since it helps to protect the condom from oxidation and does not dry out. The optimum amount of lubricant depends on the needs of the user and the type of sex act that is being performed.

The purchaser needs a specification that reflects a combination of actual measurable quantity and viscosity (reluctance to flow). If the viscosity of the lubricant is too high, the consumer may complain of stickiness. If on the other hand it seems excessive and drips off the condom, this may be partly due to low viscosity.

WHO specifies that the quantity of lubricant, including powder, in the condom package should be in the range 550 ± 150 mg (rounded to the nearest 10 mg).

It is important not to have too much lubricant since this can compromise the integrity of the hermetic seal of the condom package, and also make the condom aesthetically unpleasant.

The powder added to the condom during the production process combines with the lubricant to give the condom a “silky” feel, and may make it easier to unroll. WHO suggests that the quantity of powder should not exceed 50 mg. Because the effects of lubricant and powder quantity are somewhat subjective, and result from a combination of factors, it is difficult to be too specific about the optimum quantity.

For this reason, WHO sets fairly wide limits on the quantity of lubricant and powder that it specifies, 550 ± 150 mg. The liberal parameters prescribed for the quantity of lubricant and powder should not be exceeded since this could compromise the integrity of the condom pack.

The test is designed to measure the total amount of lubricant in the package, not just on the condom. This is because the lubricant is believed to migrate around the rolled condom after packaging.

Buyers may wish to have acceptability trials carried out among their target consumers before finalizing their own specifications.

Attempts to raise the level of lubricant above the upper limit set by WHO are likely to result in problems in sealing the packs, and the condoms may drip when taken out of the pack. In some markets, lower lubricant levels (as little as 100 mg) are preferred.

6.4.7 Spermicidal lubricants

There is evidence to suggest that the use of spermicidal lubricant in condoms is inappropriate for the following reasons:

- Spermicides can cause irritation of mucous membranes, which may reduce acceptability and increase the risk of infection.
- Most spermicidal lubricants will dry up when exposed to air. Therefore, they are exceptionally dependent on package integrity.
- Shelf-life of condoms with spermicidal lubricant is limited by the shelf-life of the spermicide.
- Evidence suggests that surfactant spermicides weaken package seals.

** Refer to the WHO Fact Sheet No. 1 for more information on lubricants.*

6.5 Packaging requirements

6.5.1 Materials for the individual condom package

It should be borne in mind that plastic material (transparent or opaque) without aluminium foil will not be completely impermeable to oxygen and will not give adequate protection to the condoms during storage.

The thickness of aluminium foil should be at least 8 micrometers and can be reduced only at the cost of increasing the risk of fracture, and thus loss of impermeability. The foil must be protected from mechanical damage by means of a plastic

layer of sufficient strength to prevent creasing and tearing during normal storage and handling.

The package should be hermetically sealed and impermeable to oxygen, ozone, water, vapour, ultraviolet light and visible light.

Any alternative packaging should be oxygen and UV impermeable, and square, if the condoms are intended for tropical climates. They should resist damage by creasing.

Rectangular packages hold the condom in a distorted shape. There is evidence to suggest that oxidation and adhesions due to shelf vulcanization can increase the risk of weakness at the points where the distortion occurs.

WHO specifies that:

Individual packages shall be square and not distort the rolled condom.

Packages must be opaque and not transparent.

6.5.2 Packaging for delivery

Every purchasing organization will have its own requirements for the various levels of packaging needed to enclose and protect the individual condom packages. WHO has a stringent specification to cover all its condom purchases. This may not necessarily be appropriate for other buyers, although it may be useful for reference when buyers are uncertain which to choose among several options.

Some buyers may require consumer packs for programmes with social marketing or commercial retail sales components.

The *WHO Specification* of these packs requires the design of a brand name and logotype, user instructions and other marketing considerations. Consumer packs typically contain 3, 6 or 12 condoms, although other quantities are sometimes specified. As with the design of the package, marketing considerations determine the number of condoms the consumer pack should contain.

WHO specifies that all packages must include the lot number, the date of manufacture (month and year) and the date of expiry (month and year).

Packages must include plastic layers, and a layer of aluminium foil at least 8 micro-meters thick.

The package must be hermetically sealed.

The condom package should be visually inspected to verify the required aspects of package quality.

It is clearly important that the condoms should be shipped in cartons that will protect them from all types of weather, careless handling and, as far as possible, atmospheric conditions, during transport and storage. Refer to *WHO Specification* Section 2 for requirements for shipping cartons and packaging.

WHO specifies that all packages must include:

- lot identification number;
- the date of manufacture (month and year);
- the date of expiry (month and year);
- text in languages specified by the purchaser;
- all markings should be legible.



Photo: Anubhav Series

Section 2

The WHO Specification

This section contains a *WHO Specification* suitable for the procurement of condoms for use in social marketing programmes and public sector STD/AIDS prevention and family planning programmes. WHO uses this specification for its own purchases.

General and performance requirements detailed in the *WHO Specification* address fundamental aspects of safety and efficacy and should not be changed. National and internationally funded programmes and purchasing agencies wishing to buy condoms should apply the entire section to their tender documents.

Design requirements may be changed within reasonable limits to address special needs of users and programmes.



Testing Condoms

Photo: Studio Five

Condom Specification

1 General Requirements

Suppliers shall follow an appropriate code of quality management, including GMP (e.g. ISO 9000 series or equivalent) and statistical process control, in the manufacture and packaging of condoms.

The methods used to test for compliance are:

- use of random samples; or
- subjective inspection; or
- documentary evidence, such as comprehensive reports of stability tests, certificates of purity from material suppliers, or certification by regulatory agency or an independent body.

Tests or verifications in this section will be carried out at the *pre-qualification* stage and during *periodic audits* if the quality of the product is in doubt once it has been purchased.

1.1 Constituent materials

The condoms shall be made from natural rubber latex.

The latex shall be free of embedded solid impurities and discoloration.

The condoms shall not liberate toxic or otherwise harmful substances under normal conditions of use, and must be in strict compliance with the applicable portions of the US Code of Federal Regulations 21 or its equivalent.

The compounding materials (colouring agents, antioxidants, accelerators, vulcanizing agents and other additives) shall not have a deleterious effect on the condoms, nor shall they have a harmful or irritating effect on the human body. It should be noted that cases of allergic

dermatitis have been associated with the following accelerators: mercaptobenzothiazole, tetramethylthiuram, and zinc dithiocarbamate. Excess accelerators and other leachable chemicals should be avoided. (Future editions of this specification may contain a test and requirements limiting excess leachable chemicals.)

Manufacturers shall take steps to minimize the level of residual proteins. (Future editions of this specification may contain a test and requirements limiting excess proteins.)

All materials must comply strictly with the requirements of the applicable portions of the US Code of Federal Regulations (USCFR) 21 or its equivalent.

These requirements will be verified by documentary evidence.

1.2 Shelf-life

It is intended that condoms purchased under this specification should retain their properties when exposed in their individual packages to an average temperature of 35° C for the stated shelf-life.

The manufacturer shall stipulate a shelf-life, measured from the month of manufacture, during which the packed products will be stable in properties and will continue to meet the requirements of clause 2.1 (before oven conditioning). This shelf-life shall be at least 3 years.

The manufacturer shall make available to the purchaser, on request, data to support the stated shelf-life. This data may take the form of:

- i. Real-time stability studies conducted over the stated shelf-life at 35° C

- ii. Accelerated studies conducted over shorter times at higher temperatures. These should preferably be done at 70° C at multiple intervals over 21 days and at a temperature between 40° C and 50° C, at multiple intervals (e.g. every 2 weeks), for at least 6 months. The basis for any extrapolation to real environmental temperatures should be stated,
- iii. Use of the methods of ISO 11346.

The maximum acceptable decrease in mean inflation properties should be 25%, and products should comply with the requirements in clause 2.1 at the end of the stated shelf-life. (Alternative requirements may be accepted at the purchaser's discretion.)

Updated documentation on 35° C post-market trials must be made available to the purchaser on request. *Validated expiry dates up to 5 years will be allowed.*

Note: Future editions of the *WHO Specification* will require specific tests to validate claimed shelf-life, and real-time stability studies at 35° C.

1.3 Resistance to oxidation (independent of the package)

Sampling

One hundred (100) condoms

Testing

Remove the condoms from their packages. Place the rolled condoms in an oven at 70° C \pm 2° C.

After 2 days, remove 50 condoms from the oven, allow them to cool for 12 – 96 hours and test them by air inflation according to

ISO 4074. After a further 7 days, remove the remainder from the oven and test them as above.

Requirement

The ratio of the mean burst pressure at 9 days to the mean burst pressure at 2 days should not be less than 75%

1.4 Dressing materials

The dressing materials applied to the condoms (e.g. powders and lubricants) shall not have a deleterious effect on the condoms, nor shall they have a harmful or irritating effect on the human body.

These materials shall comply strictly with the requirements of the applicable portions of the US Code of Federal Regulations (USCFR) 21 or its equivalent.

The manufacturer shall use a suitable powder (e.g. cornstarch, silica, magnesium carbonate) to improve the “feel” of the condom and facilitate unrolling. WHO suggests that the quantity of powder should not exceed 50 mg.

Talc and Lycopodium spores shall not be used.

Documentary evidence is required to verify the quality of the dressing materials.

1.5 Workmanship

The condoms and their packaging shall be free of defects that affect their durability, detract from their appearance, or impair their serviceability.

Condoms and the packaging should be visually inspected

Condom Specification

2 Performance Requirements

Condoms purchased under this specification must not leak or break during use, and must retain their properties when exposed in their individual packages to average temperatures of 35° C at maximum humidity for the stated shelf-life.

These properties can only be determined directly through human use trials, but are verified by means of the laboratory tests specified below. Allowance is made for a very small number of non-compliers, reflecting the state of the art of the manufacturing process as assessed by national and international standards authorities.

The properties listed in this section are deemed to be especially critical to the safety and efficacy of condoms and should not be changed.

- Performance requirements will be tested for compliance by the use of statistical samples and prescribed test protocols.
- Tests or verifications in this section will generally be undertaken at the pre-qualification stage, and by lot-by-lot compliance testing carried out by the purchaser's laboratory or by a third-party laboratory selected by the purchaser prior to delivery.
- Unless otherwise indicated, test protocols will be according to ISO 4074 (version current at the time of contract).

2.1 Bursting volume and pressure

Sampling

For the test before oven conditioning: ISO 2859-1 General Inspection Level G-1.

For the test after oven conditioning: 80 condoms per lot. (The purpose of this test is to check for major formulation or vulcanization errors.)

Testing

In accordance with the inflation test and oven conditioning procedure in ISO 4074.

Requirement

Before ageing, AQL 1.0% applied separately to volume and pressure non-compliers.

The minimum permitted bursting volume depends on the width of the condom.

For the test *before* oven conditioning, the specification prescribes a minimum limit for each condom tested. The minimum bursting pressure shall be 1 kPa. The minimum volume is arrived at by the following formula:

$$\text{minimum limit (litres)} = \frac{W^2}{150}$$

W is the lot mean width of a sample of 13 condoms, rounded off to the nearest 0.5 mm, of the shank portion of the condom measured 70 ± 5 mm from the open end, determined in accordance with ISO 4074.

A table showing the minimum bursting volume for mean width (W) from 47.0 mm to 56.0 mm is given in Appendix II.

After oven conditioning, the mean burst volume and pressure shall be at least 80% of the corresponding parameter determined from the test before oven conditioning.

2.2 Freedom from holes

Sampling

ISO 2859-1 General Inspection Level G-1, but at least code level M.

Testing

The test is carried out in accordance with ISO 4074.

Requirement

AQL 0.25%.

2.3 Package integrity

Sampling

ISO 2859-1 Special Inspection Level S-3.

Testing

Sample condoms in individual packages are placed in an airtight, transparent container (such as a laboratory Bell jar) and subjected to a vacuum of 90 ± 5 kPa (gauge) for a period of one minute.

Condom packs should inflate and remain inflated for the period of the test.

Packs that do not inflate or do not remain inflated are considered to be non-compliers. It is permissible to repeat the test on any packs not giving a clear result.

Requirement

AQL 2.5%

Condom Specification

3 Design Requirements

The design properties listed below should be adapted to reflect the specific needs of the purchaser's programme and population of intended users.

The purchaser, as part of the purchase agreement or before delivery of the product, must approve any variances in these properties.

- The methods used to test these requirements for compliance will be:
 - visual inspection; or
 - the use of random samples and prescribed test protocols.
- Tests or verifications in this section will generally be:
 - at the pre-qualification stage;
 - compliance lot-by-lot testing carried out by the purchaser's laboratory or by a third-party laboratory selected by the purchaser prior to delivery;
 - periodic audits if the quality of the product is in doubt once it has been purchased.

Unless otherwise indicated, test protocols will be according to ISO 4074 (version current at the time of contract).

3.1 Shape and texture

The surface of the condoms shall be smooth throughout.

The condoms shall have straight and parallel sides, without constrictions, and with a visible shoulder leading to a reservoir pouch at the tip.

3.2 Bead

The open end of the condom shall have a thickened ring of latex, called a bead.

3.3 Colour and clarity

The condoms shall be translucent (clear) and without added colouring

3.4 Odour and taste

The condoms shall be odourless to the degree approved by the purchaser at pre-qualification.

The condoms shall not give off an unpleasant odour when the package is opened at any time after storage for the stated life of the product.

The purchaser or the purchaser's agent will store 100 condoms at room temperature from each pre-qualified lot for use in resolving disputes.

The condoms shall be free from taste.

3.1 – 3.4 verify by visual inspection

3.5 Length

Sampling

According to ISO 2859-1 Inspection Level S-2.

Testing

According to the length measurement procedure in ISO 4074

Requirement

A minimum of 180mm with an AQL of 1.0%.

3.6 Width

Sampling

According to ISO 2859-1 Inspection Level S-2.

Testing

According to the width measurement procedure in ISO 4074

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%

(*Note: for some populations a minimum length of 170 mm together with a width of 49 mm is specified by WHO.)

3.7 Thickness

Sampling

ISO 2859-1 Inspection Level S-2.

Testing

The measurement of thickness is cones with a micrometer mounted on an anvil, with a foot diameter between 3.0 mm and 7.0 mm and a resolution of at least

0.002 mm, operating with a pressure of 22 ± 4 kPa on the sample.

For convenience, the double-wall thickness may be measured and divided by two. The samples should be wiped once with absorbent tissue, inside and out, before measuring.

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.

The individual measurements, and the average of all three, are recorded for each sample.

Requirement

AQL 1%

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

3.8 Quantity of lubricant, including powder

Sampling

ISO 2859-1 Inspection Level S-2.

Testing

The condoms in their packages are weighed on an analytical balance. The packages are then opened and the condoms removed.

The condoms and packages are washed in denatured ethanol or isopropanol until all lubricant is removed, dried to a constant mass, and then weighed again. All weights shall be recorded to the nearest 10 milligram (mg).

The mass of lubricant and dressing material will be the difference in weight of the condom and package before and after washing. Washing and drying may be repeated up to a total of four times if necessary to assure complete removal of lubricant. Alternatively, an ultrasonic bath may be used for washing, provided the washing time has been validated against repeated manual washing. For initial validation of either method, weighing is conducted after each drying.

Requirement

The condom shall be lubricated with a quantity of silicone fluid having a viscosity between 200 and 350 CS. Powder should not exceed 50 mg.

The quantity of lubricant, including powder, in the package shall be 550 ± 150 mg, rounded to the nearest 10 mg with an AQL of 4.0%.

3.9 Individual package materials and markings

Sampling

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 shall be as specified by the buyer.

Individual packages shall be square and shall not distort the rolled condom.

The packages shall be constructed of a laminate which includes a layer of suitable impermeable flexible aluminium

foil of a minimum thickness of 8 micrometers, and layers of plastic materials suitable for the mechanical protection of the metal foil and for printing and sealing.

The package shall be hermetically sealed and impermeable to oxygen, ozone, water vapour, ultraviolet and visible light.

Any lot numbers on packages must *be printed at the time of packaging* - not pre-printed.

In addition, the following shall apply:

- There shall be no evidence of leakage and 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 which allow the packages to be separated by hand without interfering with the seals.
- The package must be easy to open and can have a notch or serration to assist in opening.

The packages shall have the following markings and any other information specified by the purchaser:

manufacturer's name;

lot number or lot identification code (printed at the time of packaging, not pre-printed);

month and year of manufacture
month and year of expiry

all markings should be legible
(the year recorded as a four digit number, and the month as a two digit number).

Requirement

AQL 2.5% - Verify by visual inspection

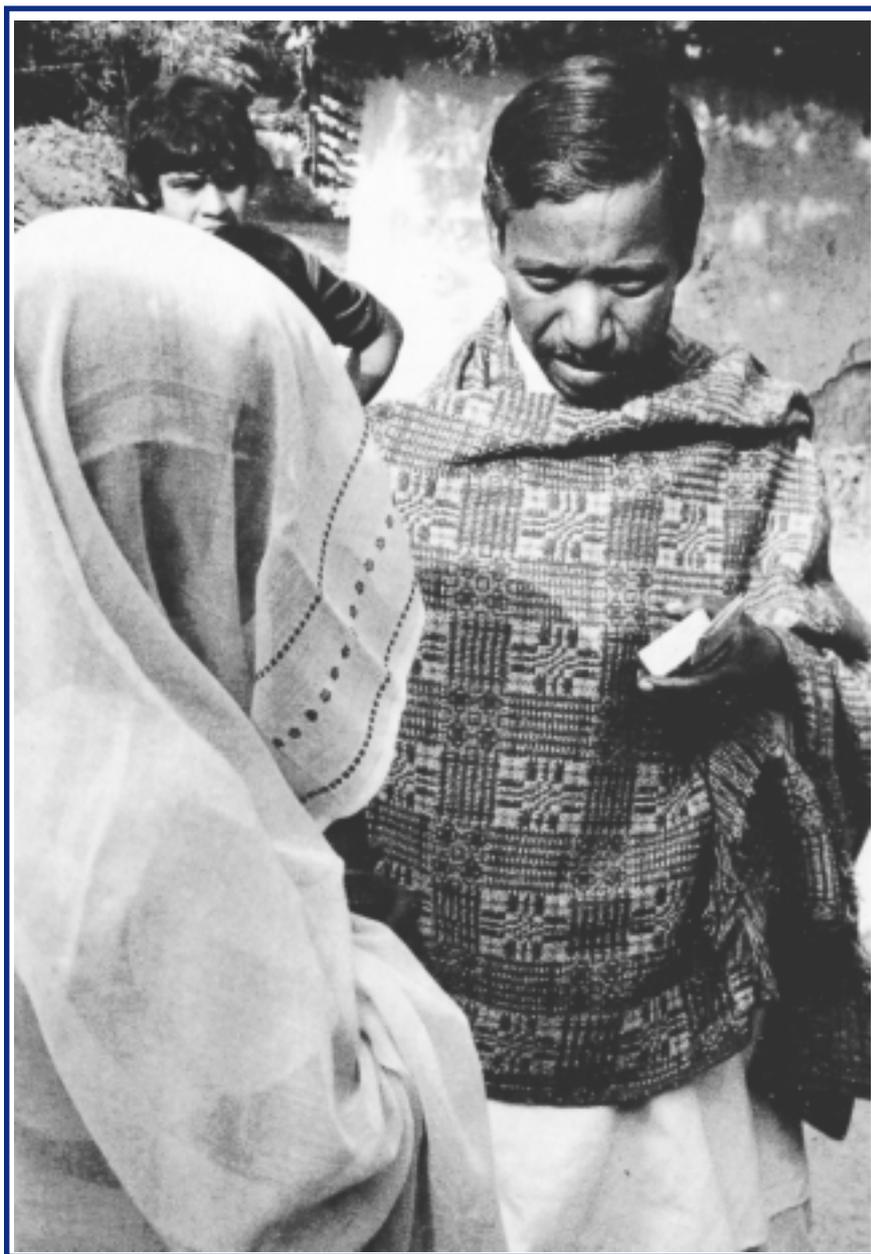


Photo: Anubhav Series

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4. Packaging for Delivery Requirements

The properties listed below will be tested for compliance by inspection. Inspections or verifications in this section will generally be carried out at the *pre-qualification* stage and during *periodic audits*.

4.1 Cartons and markings

Sampling

ISO 2859-1 Special Inspection Level S-3.

The lot size for the inspection of inner boxes or consumer packs is the number of inner boxes, and the sample unit is one inner box.

For the inspection of exterior shipping cartons, the lot size is the number of exterior shipping cartons, and the sample unit is one shipping carton.

Examination of inner boxes shall be done on boxes selected at random from sample shipping cartons. Examination of defects of closure shall be done on randomly selected shipping cartons fully prepared for delivery.

Testing

By inspection carried out at the time of sampling and/or testing.

Requirements

The individual requirements for the various packaging and packing for delivery are set out below.

The AQL for these inspections is 2.5%.

Defects found in the packaging and the marking of packages for delivery shall be assessed in accordance with the table below.

Consumer packs

No consumer packs are included in the *WHO Specification*. Specify in accordance with the requirements of the programme.

Inner boxes

Inner boxes shall hold 144 (1 gross) individual condom packages in strips of three or four or as specified by the purchaser at the time of contract.

Classification of defects in packaging and marking of packages for delivery

Examine

Contents

Marking

Materials

Workmanship

Defects

Number of condoms not as specified; packages or strips not as specified.

Omitted; incorrect; illegible; of an improper size (exterior, interior), location, sequence, or method of application.

Packaging/packing materials not as specified, missing, damaged or non-serviceable.

Shipping cartons inadequately closed and secured; poor application of internal packaging and packing material; distorted intermediate packages.

- 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.
- 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.

Exterior shipping cartons

The inner boxes shall be packed into plastic or other waterproof lining bags, which will be placed in three-wall 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-wall corrugated fibreboard available is not of sufficient strength and rigidity to meet stacking requirements or to resist being cut at the corners when the plastic strapping is applied. In such cases, an inner carton of two-wall 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

Condom Specification

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.

4.2 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, palleting of discrete lots or otherwise physically linking all exterior shipping cartons from discrete lots, and issuing instructions to this effect to shippers and warehouse personnel.

The Male Latex Condom

Table 2 Summary of requirements for which tests are specified

Specification	#	Sampling	Testing	Requirements	AQL
General Requirements	1				
Constituent materials	1.1			Documentation	
Shelf-life	1.2	3 lots / 650 each	see Specification 1.2	Documentation	
Resistance to oxidation	1.3	100 condoms	see Specification 1.3	P (9days) - P (2days) <25%	
Performance Requirements	2				
Bursting volume	2.1	G-1	ISO 4074 Specification 2.1	$\frac{\text{width}^2}{150}$	1.0
Bursting volume 70° C / 7 days	2.1	80 condoms	ISO 4074	<20% drop	
Bursting pressure	2.1	G-1*	ISO 4074	1kPa	1.0
Bursting pressure 70° C / 7 days	2.1	80 condoms	ISO 4074	<20% drop	
Freedom from holes	2.2	G-1*	ISO 4074 Specification 2.2	no holes	0.25
Package integrity	2.3	S-3	see Specification 2.3	no leaks	2.5
Design Requirement	3				
Length	3.5	S-2	ISO 4074	180mm	1.0
Width	3.6	S-2	ISO 4074	53 ± 2mm; mean ± 1mm	1.0
Thickness	3.7	S-2	see Specification 3.7	0.065 ± 0.015mm	1.0
Lubricant plus powder	3.8	S-2	see Specification 3.8	550 ± 150 mg	4.0
Packaging Requirement	4				
Package Materials and Markings	4.1	S-3	Specification 3.9 Specification 4.1	Visual Inspection	2.5

G-1 at least code M*

Appendices



Condom Finishing

Photo: London International Group

Appendix I

A Review of Some Methods Proposed 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 laid down. 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.

A selection 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, or a reputable statistical quality control consultant, or both.

The reduction in 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, should 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 which, 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 level during the testing of a consignment. This increases the need for communication between the buyer, sampling agency and testing laboratory; and can lead to long and costly delays, especially when the various parties to the procurement are in different countries or, indeed, on different continents.

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 for one seriously flawed batch to be acceptable 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 with 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 latter 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 is a relatively simple schemes, which also retain a sample size sufficient to give a good estimate of process averages 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 of tests, reviewing in-process test data and verification of calibration.

The inspector must be an experienced independent testing expert. His/her arrival at the factory must always be unannounced, and he/she must always take suitable samples 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 shall pass all tests.

At the same time, the entire shipment shall be subjected to the aggregate analysis described in 2.1 Samples will be drawn from every lot and sent to the testing laboratory, which will be instructed to test only the agreed proportion. The remainder of the samples will be set aside in case it is necessary to resume more intensive testing due to failures.

If any lot tested fails one of the performance tests, full lot-by-lot testing shall be resumed immediately for all lots making up the shipment. The procedure for 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.

Appendix II

Minimum Burst Volume

<i>Mean Condom Width Lot Average</i>	<i>Burst Volume (litres) Individual Minimum Before oven conditioning</i>
<i>47.0</i>	<i>14.5</i>
<i>47.5</i>	<i>15.0</i>
<i>48.0</i>	<i>15.5</i>
<i>48.5</i>	<i>15.5</i>
<i>49.0</i>	<i>16.0</i>
<i>49.5</i>	<i>16.5</i>
<i>50.0</i>	<i>16.5</i>
<i>50.5</i>	<i>17.0</i>
<i>51.0</i>	<i>17.5</i>
<i>51.5</i>	<i>17.5</i>
<i>52.0</i>	<i>18.0</i>
<i>52.5</i>	<i>18.5</i>
<i>53.0</i>	<i>18.5</i>
<i>53.5</i>	<i>19.0</i>
<i>54.0</i>	<i>19.5</i>
<i>54.5</i>	<i>20.0</i>
<i>55.0</i>	<i>20.0</i>
<i>55.5</i>	<i>20.5</i>
<i>56.0</i>	<i>21.0</i>

Appendix III

Regional or Ethnic Differences in Erect Penis Size

<i>Percent of sample</i>				
<i>Penis size</i>	<i>Caucasian/USA^a</i>	<i>African/USA^a</i>	<i>Australia^b</i>	<i>Thailand^c</i>
<i>Length (mm)</i>				
<i>75-100</i>	<i>0</i>	<i>0</i>	<i>0</i>	<i>3</i>
<i>101-125</i>	<i>3</i>	<i>0</i>	<i>4</i>	<i>27</i>
<i>126-150</i>	<i>27</i>	<i>15</i>	<i>28</i>	<i>51</i>
<i>151-175</i>	<i>53</i>	<i>59</i>	<i>47</i>	<i>17</i>
<i>176-200</i>	<i>15</i>	<i>21</i>	<i>20</i>	<i>2</i>
<i>>200</i>	<i>2</i>	<i>5</i>	<i>1</i>	<i>0</i>
<i>Circumference (mm)</i>				
<i><75</i>	<i>2</i>	<i>2</i>	<i>0</i>	<i>0</i>
<i>76-100</i>	<i>3</i>	<i>2</i>	<i>0</i>	<i>16</i>
<i>101-112</i>	<i>13</i>	<i>9</i>	<i>5</i>	<i>37</i>
<i>113-127</i>	<i>53</i>	<i>53</i>	<i>27</i>	<i>30</i>
<i>128-137</i>	<i>10</i>	<i>11</i>	<i>28</i>	<i>14</i>
<i>138-150</i>	<i>14</i>	<i>14</i>	<i>26</i>	<i>3</i>
<i>>150</i>	<i>5</i>	<i>9</i>	<i>14</i>	<i>0</i>

a Source: The Kinsey data - marginal tabulations of the 1938-1963 interviews conducted by the Institute for Sex Research (1979). Circumference measured at maximum point.

b Source: Richters J, Gerofi J, Donovan B. Are condoms the right size(s)? A method for self-measurement of the erect penis. Venereology, 1995, 8(2):77-81.

c Source: Bangkok Medical University (1979). Circumference measured at base.

Appendix IV

Glossary of Terms

Acceptable quality level (AQL)

The AQL is defined in ISO 2059.1 as: when a series of lots is considered, the quality level for which for the purposes of the sampling inspection is the limit of a satisfactory process average.

Highest percentage of non-compliers which is acceptable in the longer term.

Acceptance number

The highest number of non-compliers (failures) allowed in a specific test from a selected sample.

Lot (sometimes called batch)

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;*
- have the same dimension, colour, shape and surface texture;*
- be manufactured on the same production line;*
- be vulcanized under identical conditions;*
- be manufactured within a period of 24 hours.*

Manufacturers must declare their nominal lot size when tendering for an order. However, any interruption in production must result in a new lot being started. Lots must not be made up from separate interrupted runs; lot sizes may be allowed to vary within limits to allow for problems on the production line.

In the case of smaller manufacturers, or manufacturers operating small, low-volume plants, the limit of 24 hours may be extended, or the production of two parallel lines may be combined, to enable a lot of economic size to be assembled. In either case, the manufacturer must demonstrate homogeneity of production between the consecutive periods or the two lines.

Lot number or code

A unique identifying alphanumeric code assigned to a batch or lot.

Bead

The thickened ring formed at the open end of the condom.

Clarity

The relative transparency or opacity of the latex film.

Natural latex rubber condom

A sheath, made of natural latex rubber, designed to cover the erect penis during sexual intercourse to prevent conception and the transmission of sexually transmitted diseases including HIV, the virus that causes AIDS.

Consumer pack

A package containing a number of individual packs of condoms, such as 3, 10 or 12.

Exterior shipping carton

The container into which a number of inner boxes are packed, suitable for transport by air, sea or road, and subsequent storage.

Good manufacturing practice (GMP)

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.

Many countries have a code of good manufacturing practice. Alternatively, reference can be made to the ISO 9000 series of documents, which are listed in Appendix V, Applicable documents.

Individual package

The sealed packet enclosing an individual condom.

Inner box

A box used to contain a convenient number of condoms in individual packages or consumer packs. Inner boxes typically contain 100-200 condoms (WHO, in common with many other purchasers and most of the condom industry, uses the gross - i.e. 144 condoms - as its unit of purchase and routinely specifies inner boxes containing 144).

Inspection level

The degree of examination of the batch, as specified in ISO 2859-1. The higher the inspection level, the more stringent the testing, and hence the lower the risk of faulty products reaching the consumer.

Length (of condom)

The length of the condom measured from the open end to the tip, but excluding any reservoir.

Modulus

The stress required to produce a unit strain, i.e. a change in length. Low modulus rubber stretches more easily.

Reservoir

The narrowed portion of the condom at the closed end, designed to contain ejaculate. The reservoir is sometimes called the teat.

Tensile

Capable of being stretched.

Viscosity

The frictional resistance that a fluid in motion offers to an applied sheer force.

Wall thickness

The thickness of the latex film.

Width (of condom)

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.

Note: In the case of flared condoms, a separate width dimension in the middle of the flared portion must be specified, and measured during testing.

Appendix V

Applicable Documents

Various external documents form part of the WHO Specification for Condoms, 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: International Organization for Standardization, Case Postale 56, 1211 Geneva 20, Switzerland, or the national standardisation organisation in the buyer's country.

Testing methods:

ISO 4074-2 Determination of Length

ISO 4074-3 Determination of Width

ISO 4074-5 Testing for Holes

ISO 4074-6 Determination of Bursting Volume and Pressure

Sampling:

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

ISO 2859-3 Skip lot sampling

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 9002 Quality Systems - Model for Quality Assurance in Production and Installation

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 WHO Specification for Condoms and may be cited in an invitation to bid, or an order, issued by a buyer.

Regulations on toxicity and tissue irritation (e.g. US Code of Federal Regulations USCFR 21).

Freight classification.

Regulations for medical devices (if applicable).

Local code of Good Manufacturing Practice.

Any other documents which are relevant under the law or regulations of the purchaser's or the destination country.

Appendix VI

Documents and Resource Material Available from WHO and Other Agencies

Buyers and others concerned with condom procurement and programming who want to study some of the subjects dealt with in the WHO Specification in greater depth can obtain the following reports from Family and Reproductive Health, World Health Organization, 1211 Geneva 27, Switzerland.

WHO/RHT/FPP/98.15

10 Condom Programming Fact Sheets.

Monograph – The Male Latex Condom

WHOGPA/GCO/PVR/95.8

Rapid Assessment Protocol for Planning Condom Programming.

WHO/GPA/TCO/PRV/95.7

Guide to Condom Programming.

WHO/GPA/CNP/92.5

Guide to Adapting Instructions on Condom Use.

Information Pack: The Female Condom.

WHO/HRP/TDA/97.1

Pre-clinical and clinical requirements for approval to market non-latex condoms.

UNAIDS Best Practice Guides.

Other Sources of Resource Material.

*Centers for Disease Control and Prevention,
Programme Services and Evaluation,
Division of Reproductive Health,
1600 Clifton Road,
NE (Mailstop K-22),
Atlanta, Georgia 30030, USA.*

*Crown Agents Services Ltd.,
Training Division,
St. Nicolas House, St. Nicolas Road,
Sutton, Surrey, SM1 1EL,
United Kingdom.*

*Family Health International,
P.O. Box 13950,
Research Triangle Park,
North Carolina 27709, USA.*

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

*Program for Appropriate Technology
in Health (PATH),
4 Nickerson Street,
Washington, 98109 - 1699, USA.*

*UNFPA,
Technical and Evaluation Division,
Reproductive Health Branch,
220 East 42nd Street,
New York, N.Y. 10017, USA.*

*UNAIDS,
20 Avenue Appia,
CH-1211 Geneva 27,
Switzerland.*



Photos: UNFPA