NATIONAL CONDOMS POLICY AND MANAGEMENT GUIDELINES

health
Department:
Health
REPUBLIC OF SOUTH AFRICA

CONTENTS

1. PREFACE

South Africa has one of the largest national-level public sector condom procurements per capita globally, and the program is well established. Condom uptake within the general population of South Africa is high in comparison to other countries, and condoms are widely available throughout the country. Male and female condoms are available in the country. Male condoms are widely available all health care facilities and other institutions and organizations, whereas female condoms are available in selected health care facilities only. Given South Africa's high levels of HIV prevalence, there is a critical need to ensure that condoms should be consistently used in all potentially risky sexual encounters.

The National Department of Health (NDOH) is committed to ensuring that male condoms are readily available and easily accessible to all communities and individuals across South Africa on a sustained basis. Condoms distribution is implemented in line with principles of equity and social justice. It is recognized that the NDOH procures condoms on behalf of the public from tax revenues. As such, individuals have the right to protect themselves by having access to high quality condoms on a continuous basis. This rationale dictates the provision of condoms free of charge to the public.

The successful implementation of the condom program requires a strong network of partnerships between government, NGOs, and the private sector. The goal of condom programming is to ensure that sexually active persons at risk of HIV/STIs are motivated to use condoms, have easy access to quality condoms, and can use them consistently and correctly. The present guidelines aim to set a platform that facilitates the engagement of all stakeholders with the national condom distribution program. In developing these guidelines, a wide range of stakeholders were involved, they are hereby complimented for their valuable contributions.

I wish to thank the core team from the STI-HIV Prevention Unit of the HIV&AIDS Directorate that spent many days, weeks and months in the production of this document. I also thank our valued partner, the UNFPA and its staff members who funded the development of these guidelines. In addition, I recommend the routine use of these guidelines by all involved in the management of condoms and hope their implementation will lead to an improvement in the distribution and use of condoms.

Director-General
NDOH
March 2011

2. BACKGROUND

The HIV epidemic is a great challenge to South Africa's demographic future and economic growth. It is now regarded as a hyper-endemic disease (UNAIDS, 2010). Based on the most recent survey, the HIV prevalence is 16.9% among people aged 15-49 years old (HSRC, 2009).

The South African National Department of Health (NDOH) has been implementing a national-level condom procurement and distribution program since the early1990s. This program has been rapidly expanded over the past two decades. Male condoms distributed through the public sector to primary sites per annum were 308 million in 2007/08; 283 million in 2008/09; and 445 million in 2009/10. Recent annual distribution has approached 400 million per year, representing about 70% of the condoms used in the country were distributed through the public sector; while, 122 000 female condoms were sold at subsidized rates as part of the national condom social marketing program conducted by Society for Family Health (SFH).

Because condoms are useful in providing double protection against sexually transmissible infections and unwanted pregnancy, both the previous National HIV/AIDS Strategic Plan of 2000-2005, and the current plan of 2007-2011 have placed emphasis on the promotion and dissemination of male and female condoms. In June 2004, a new 'branded' public sector male condom - *choice*™ - was launched, targeting the youth 18-35 year olds with promotional messages included in the Khomanani Campaign. These promotion activities have been successful in increasing condom use by youth and adults of all ages. For instance, in a survey conducted in 2008, 87% of males, aged 15-24 reported using a condom in their last sex act – perhaps the highest use in the world. This high level of use has already produced a significant drop in incidence of HIV among teens in the country – a significant achievement.

However, many issues still need to be dealt with in order to increase and maintain a high level of condom use as a strategy to reduce new HIV infections. Among the key issues are logistics management problems, as well as socio-cultural determinants of sexual behavior. In 2008, some delays in tendering and contracting processes resulted in shortage of condoms. A decade earlier, millions of condoms had to be recalled because of defects. Condom use is itself influenced by a number of factors including socioeconomic development; urbanization; women's education level and status in society; cultural norms and beliefs; as well as the knowledge and attitude of users. From international and national literature, some of the known obstacles to effective and widespread condom use include:

- Societal disapproval of condoms, including social and cultural beliefs and norms that restrict or stigmatize condom use. In some cultures, condom use is perceived as not 'macho', especially where ejaculation of semen into the vagina is considered to be an essential, mandatory part of the sexual act
- Lack of control over male condom use — often arising from unequal power relations between men and women, from lack of negotiating skills, or from societal disapproval of women proposing condom use
- Incompatibility of regular condom use with the natural need for procreation
- Implications for trust about fidelity in stable partnerships (i.e., users fear that insisting on using a condom will be interpreted as a lack of trust in their partner; or that female condoms will make women to become promiscuous)

- Difficulties in obtaining condoms arising from high prices, restricted availability, and lack of privacy at the point of sale or distribution;
- Personal reluctance to use condoms because the users believe that condoms reduce sensitivity or are uncomfortable or disruptive to spontaneous love-making, or simply the lack the necessary skills in correct use or in handling condom failures
- Poor or inappropriate quality or design of condoms that raise public concerns on safety

The above issues coupled to a lack of logistics and warehousing management skills at provincial and primary distribution sites levels, a lack of systems for inventory management and tracking, and human resources shortage particularly at PDSs level, constitute some of the challenges that affect the performance of the Condom Procurement and Distribution Program.

Hence, the development of these National Condom Policy and Management Guidelines is informed by the need to provide a national framework within which the procurement and distribution of condoms will be managed taking into account other policy documents and relevant legislation. The following laws, regulations, and policy documents affect the promotion and distribution of condoms:

- The Constitution of South Africa
- Batho-Pele ('People First'), 1999
- National STI, HIV and AIDS Strategic Plan 2007-2011
- National Patient's Rights Charter
- Child Care Act , 1983 (Act no. 74 of 1983)
- Children's Act 38 of 2005 as Amended
- Policy guidelines for Youth and Adolescent Health
- National Contraception Policy Guidelines

3. GOAL AND OBJECTIVES OF THE GUIDELINES

3.1. Goal

- To provide a framework within which the procurement and distribution of condoms is managed in order to reduce sexual transmission of HIV and other sexually transmitted infections

3.2. Objectives

Objective 1: To foster an enabling policy environment for condoms promotion and distribution

Objective 2: To ensure adequate funding/financing for condoms

Objective 3: To ensure a smoothly operating supply chain management of condoms

Objective 4: To ensure correct estimation of condoms needs

Objective 5: To ensure that condoms are purchased at the lowest available price

Objective 6: To ensure that only high-quality condoms are made available to the public

Objective 7: To ensure effective distribution, warehousing, and issuing of condoms at PDS/SDS

Objective 8: To remove barriers that restrict access and use of condoms

Objective 9: To ensure the monitoring and evaluation of condoms management program activities

Objective 10: To ensure that relevant operational research is conducted to inform policy, and practices

4. DETAILED POLICY GUIDELINES

4.1. Policy environment for condoms promotion and distribution

4.1.1. Objective: To foster an enabling policy environment for condoms promotion and distribution

The right of all individuals to freely access condoms can be hindered through incompatible legislation, and policies; or through inefficient logistics or supply chains. Since legislation, regulations, and strategic policy guidelines define the policy environment, it is essential that guidelines in health and related fields should support and complement one another so that they act synergistically to improve reproductive health and uphold the human rights of citizens and empower them to protect themselves from HIV and other infections.

4.1.2. Strategies

- Advocate for visible demonstrations by policymakers of commitment to family planning and condoms promotion through statements by national leaders
- Advocate the inclusion of condom promotion and distribution in development strategy documents
- Foster a supportive environment for greater involvement of the commercial and private sectors in addressing condoms promotion and distribution
- Build the capacity of decision-makers and civil society in decentralized settings so that condoms promotion remains a priority at provincial and local government levels
- Collect and use timely data and information to be used as the basis for awareness-raising by and for civil society and for evidence-based decision-making by policymakers
- Familiarize elected civil servants on the rationale to support condoms promotion and distribution, with emphasis on their the economic and health benefits
- Review and revise existing legislation to allow full implementation of the present policy guidelines

4.2. Financing and funding the purchase of condoms

4.2.1. Objective: To ensure adequate funding for condoms

Financing mechanisms to achieve sustainable supply of condoms are needed in response to a changing development assistance environment. It is important that the national government takes the responsibility for funding the purchase of condoms, both male and female. Likewise, individuals themselves should have the choice to purchase condoms if or when necessary using a variety of financing options. To ensure adequate funding for condoms:

4.2.2. Strategies

- Advocate the inclusion of the financing of female condoms in development and poverty reduction strategies as a way of ensuring that condoms promotion remains on the national agenda

- Advocate with relevant government officials to include a budget line items for female and male condoms and work to ensure that the funds allocated are adequate and expended on condoms
- Include female and male condoms in the South African Essential Drug Lists so that public funds can support the reproductive health needs of women and men
- Incorporate family planning needs into social/health insurance programs and basic health care programs so that insured people can purchase condoms with their medical aids funds

4.3. Condoms Supply Chain Management

4.3.1. Objective:. To ensure a smoothly operating supply chain management of condoms

Effective logistics cycles and supply chains are essential to the success of any public health programs. A strong supply chain, with committed leadership, capable staff, necessary resources, and logistics data, would help ensure that people of South Africa can get quality condoms when they want them. Hence,

4.3.2. Strategies

- The necessary investments should be made for the development, maintenance and continuous improvement of a strong logistics management information system in order to monitor condoms availability at all levels and help minimize stock-outs and overstocks at facilities
- The personnel responsible for condoms logistics management should advocate and make policymakers aware of the need to invest in the condoms supply chain—including the recruitment of adequate number of trained managers and personnel; and the provision of the required equipment, infrastructure, and systems
- Explore and expand the range of condoms distribution networks, to include NGOs establishments, workplaces, entertainment places such as taverns, hotels, clubs; transport hubs, spaza shops, and other establishments in order to ensure that condoms are available all the times when needed.
- Incorporate condoms (male and female) into a list of "tracer drugs," as a way to monitor supply chain performance
- In order to track the distribution of condoms a logistics officer will be appointed and his/her main task will be logistics data management which entails the collection, review, aggregation, analysis, and interpretation of logistics data and the development and dissemination of logistics data reports
    - Manage central-level tools for logistics: To produce reports on logistics system performance, the reported data must be entered into a computerized or automated tool that aggregates and analyzes the data. Tools include several different options for use as a computerized LMIS. The Logistics officer is responsible for maintaining and managing all relevant tools. This includes identifying needed improvements to the tools, ensuring that there is capacity to use the tools, and managing all supporting documentation for the tools.
    - Generate logistics system progress reports for NDOH and stakeholders: The tool selected and implemented for the logistics system should assist in producing reports to be disseminated to relevant stakeholders and officers. These outputs reports are generated by aggregating and analyzing the data contained on the routine LMIS reports submitted by facilities. These central-level reports should contain information on trends in consumption, national stock status,

percentage of facilities reporting, and percentage of facilities experiencing a stock-outs. These reports should be used to identify overall logistics system weaknesses or issues to inform overall program planning and management, as well as logistics system improvements. These reports also provide logistics data necessary for decision making up and down the supply chain: by level (central, province, SDP) and by type (government divisions, implementing partners)

4.4. Condoms forecasting and quantification

4.4.1. Objective: To ensure correct estimation of needs

The main use of logistics data is to inform quantification exercises. Quantification is a critical supply chain activity that links information on services and commodities from the facility level with program policies and plans at the national level. Quantifications are used to inform higher level decision making on the financing and procurement of commodities, providing the information on how many of which products should arrive in the country at what time.

It is important that condoms needs are established by gathering and studying available data from surveys and service statistics; this information will help program managers to come up with accurate estimates of needs in order to quantify the number of units to be procured and prepare procurement plans.

As part of the plan, proper forecasting should be conducted to ensure an adequate continuous supply of condoms is procured and distributed. In addition to quantities, an assessment should be made to take into account the results of studies on the condom brand preferences if any, as well as on the ratios between female and male condoms

4.4.2. Forecasting formula

Forecasting of condoms needs will be done using demographic data, while the quantities to procure will be based on logistics data. This approach is based on the premise that consumption data are an excellent indicator of past demand and supply, while demographic data show how demand will actually change in the future, as the population increases, and people behavior changes.

In order to do the forecasting the data needed are:

• The population figures, the most recent population statistics from Statistics South Africa or the most recent UN World Population Prospects, including:

- Male population figures, 15+, in 5 year groupings were used, aggregated into groups 15-24, 25-49, and 50+ (since this is how the survey data is reported, and these grouping represent groups with different lifestyles) for male condoms; likewise female population figures for females condoms
- Projections of population in the current and next 5 years (population estimates)

- The behavioral data, the most recent data from prevalence surveys reporting data on sexual behavior (number of sexual acts or annual sexual frequency) and condom use at last (most recent) sex

The formula can be processed as follows:

- Population x sexual frequency = # of sex acts;
- # of sex acts x "used a condom last sex" = condoms used;

- Condoms used x "used a free (i.e. NDOH) condom" = NDOH condom demand
- NDOH Condoms Demand x "unit cost" = Budget to be allocated for the purchase of condoms

In order to determine the quantities of condoms to purchase, the logistics data will be used as follows:

- Aggregate Quantity on hand (QoH) = Sum of all reported quantities at the end of a quarter or specific date based on their expiry date. Condoms expiring in less than three months should be not added since it is possible that they may not be used, and are likely to expire
- Average Quantity used monthly (QuM) = Sum on monthly quantities actually reported as issued by all SDPs/3 for a quarter or /12 for a year
- Quantities in Months in stock (QMiS)= Quantities in hand based on expiry date/average monthly use
- Quantities in Months to purchase (QMtP)= 18 or 24 months, based on a 12 months lead time
- Quantities to purchase (QtP) = 18-QMiS, this can be broken down in 2-4 for supply planning

Alternatively, a quantification software such as *Quantimed* and a supply planning tool such as *Pipeline* can be used.

4.4.3. Strategies

- The NDOH should establish a Contraceptive Standing Committee made of representatives from the private sector and actors outside the health sector, especially representatives from ministries of planning and finance, and provincial officials in order to provide oversight on the condoms logistics management activities
- Conduct annual quantifications and regular updates of commodity requirements and costs: Quantification is not a one-time, annual event that ends when the final quantities and costs have been determined. One of the outputs of a quantification exercise should be an implementation plan for routine monitoring, reviewing, and updating the quantification at least every six months or more often if key data and assumptions change or the volume of condoms and their use differs greatly from the forecasted demand and actual consumption.
- A quarterly national workshop or working session meeting including provincial coordinators and other relevant stakeholders should be convened to revise the quantification and plan the procurement of condoms
- Develop and manage supply plans: A supply plan details the arrival dates and quantities of shipments from all suppliers. The Logistics officer will manage the information regarding supply plans from various suppliers to the Condom Procurement and Distribution Program. For each supplier, the following information will be captured: pack sizes, prices, and lead times.
- Routine collection of service statistics is to be conducted on a monthly basis as defined in the relevant SOPs
- Personnel responsible for condoms logistics management should develop an annual Condoms Supply and Distribution Plan that includes feasible, realistic objectives, and estimate the cost of implementing the action plan for both male and female condoms. The above personnel are responsible for implementing the existing Female condoms forecasting guidelines for estimating female condoms' needs
- Training in quantification methods should be regularly given to personnel responsible for procurement of condoms at national, provincial, district, and institutional levels

4.5. Procurement of condoms

4.5.1. Objective:. To ensure that condoms are purchased at the best available purchasing terms and prices

Contraceptive procurement is relatively complex, and involves defining specifications for each product to be procured, estimating the quantity of each product required, and managing the financial transaction between the government and the procurement agent. For this reason, the procurement process requires a high degree of expertise and experience; it is therefore necessary to build capacity for condoms procurement that includes knowledge of procurement regulations, as well as the interrelated issues of forecasting, financing, procurement, and logistics as well as preparation of bidding documents, evaluation of bids, selection of suppliers, award and management of contracts.

4.5.2. Strategies

• Build human resource capacity so that condoms procurement is efficient and streamlined at central level at the NDOH

• Advocate for the reduction or elimination of taxes on imported condoms to obtain lower commodity prices and to stimulate greater involvement of the private sector in the promotion and distribution of condoms

• Explore alternative procurement agents, such as UNFPA, that may be able to purchase condoms in greater volume and at lower prices.

• Explore the possibility of developing or participating in group contracting mechanisms or other forms of pooled procurement to obtain the lowest prices possible for condoms.

• Participate in efforts to share information with regional counterparts (such as SADC countries) about contraceptive pricing as a strategy for learning about lower contraceptive prices

- Prepare bidding documents: These documents will establish:
    - All the specifications as listed in Appendix 2 and 3 for female and male condoms respectively
    - All rules and procedures for bidding and bid opening
    - Criteria for choosing a winning bid after ranking and qualification based on the standard procurement rules of the NDOH
- Award, contracting, and financial arrangements with the winner(s) will be performed based on the standard procurement rules of the NDOH

4.6. Quality assurance and control of condoms

4.6.1. Objective: To ensure that only high quality condoms are made available to the public

There are approximately 30 national condom standards in force around the world. Committees composed of representatives from technical and scientific fields, regulatory agencies, condom manufacturers, and consumer groups write these standards. Despite the existence of these standards, poor quality of condoms may be due to inadequate manufacturing standards, or due to inadequate transport and storage conditions, and poor handling by users. These shortcomings may lead to breakage, leakage or slippage during use. The reference standards for condoms to be used in South Africa will be:

- ISO 14971-1 and ISO13485 for female condoms

- *ISO 4074 and* SANS 4074 / 2003 (SABS)

In order to ensure that high-quality condoms are made available to the public, the following strategies will be implemented

4.6.2. Strategies

- Implement the design and quality control specifications as shown in Appendix 2 and 3
- In order to enforce the above standards all prequalified suppliers will be subjected to a pre-contact inspection, and the condoms to a pre- and post delivery quality control testing
- The pre-contract inspection will be conducted by a team made of representatives from the National Department of Health, the National Treasury, the South African Bureau of Standards, and a partner NGO with expertise on condoms' matters. Its report will be used to finally award or not award the supplier contract
- No supplier can deliver condoms until the pre-delivery testing has been completed. This applies to both purchased and donated condoms that have been accepted in principle. A negative report during the post-delivery QC may result in the recall of the faulty or substandard lots. These costs of recalls will be passed on to the supplier.
- Pre-shipment compliance inspection: This will involve:
    - Site visits for locally manufactured condoms. During the visits, the inspection team will observe the packing, marking, the documentation, the quantities and general conditions of the products as well as sample some units for quality control testing
    - Pre-shipment compliance testing for imported condoms. This inspection certifies that the merchandise appeared to be in good physical condition and the contracted quantity was present immediately prior to shipment. This will involve the hiring of an independent, third party to conduct inspection and testing services in order to eliminate charges and countercharges of prejudice if there is any disagreement about the outcome of inspection or testing
- When test results, expert opinion, and review by the assigned contractor or local inspection team have established confidence in the quality and acceptability of the goods, then the suppliers or manufacturers will be given the authorization to deliver or ship the consignments of condoms as ordered

4.7. Distribution and issuing of condoms

4.7.1. Objective:. To ensure effective distribution, warehousing and issuing of condoms at PDS/SDS

South Africa imports 83% of condoms used locally; while efforts should be made to increase local capacity production, it is imperative that warehousing facilities should hold enough stock to take into account unforeseen circumstances that may affect the delivery lead time from countries where condoms are purchased.

4.7.2. Strategies

Distribution and warehousing

- Develop a strategy to foster local manufacturing of a substantial quantities of condoms
- Ensure that dedicated personnel are hired at national, provincial, district, and facilities levels to manage and issue condoms
- Establish provincial warehouses in order to increase the national storage capacity of condoms
- Upon meeting the requirements of quality assurance for pre-delivery inspection and testing, the delivery of condoms to provincial warehouses and PDSs will be done based on a pre-established schedule
- Ensure adherence to the delivery or resupply schedule: To enable commodity availability, commodities must arrive at the SDP at the right time. As part of the system design, a delivery or resupply schedule should be established. Given the outsourcing of distribution to a third party, the responsible person at the NDOH should manage contracts with the private companies and monitor performance so that these private companies must conduct on-time deliveries, and maintain product quality based on the relevant SOPs
- Staff members at PDSs and SDSs will receive condoms following the relevant SOPs
- Train PDS and SDS personnel regarding "Guidelines for proper storage of condoms and implementation of Condoms Management Standards Operating Procedures"
- Accredit new PDS and SDS based of the relevant SOP on registering of new distribution outlets

Issuing of condoms to clients

- Implement the following principles for **Issuing condoms to clients under 14 years old**

  Based on the Child Care Act 1983 (Act No. 74 of 1983) which states that: Minors of 14 years and older may consent to their own medical treatment without the assistance of parents or guardians; in practical terms, this means that children below 14 years can approach a condom distributing establishment or a health facility for sexual and reproductive health information and condoms

  In order to protect children, this policy requires that health facilities should provide sexual health information to young people under the age of 14 and to give condoms if they are sexually active. In doing so, the personnel attending to the minor should:
  - Ask the young person if they have anyone to talk to about sexual health concerns and encourage them to talk to their parents or guardians
  - Remind them about confidentiality

  Implement the following principles when **Issuing condoms to clients over 14 years and adults**
  - Any person aged 14 years or older can approach a condom distributing establishment, and collect, or be given condoms. When a client attends a health facility for condoms, the personnel may with the permission or consent of the

client assess the client's understanding of the following points and give them information as necessary on:

- How to use a condom correctly - give a practical demonstration using demonstration tools (see Condoms Demonstration Guidelines-Annexure 1)
- How condoms can prevent STIs and pregnancy
- Ways that condoms can become damaged when carrying them , and during storage
- How to manage pressure to have sex
- HIV testing
- Other sexual/reproductive health services
- Address questions raised or asked by the client

4.8. Condom promotion, social marketing, and training on condoms issues

4.8.1. Objective: To remove barriers that restrict access and use of condoms

The right of all individuals to freely access and use condoms can be hindered through incompatible legislation, policies and guidelines and through inefficient logistic systems as well as a results of individual sociocultural factors. Removal of these barriers is essential for condoms users to obtain unrestricted access to condoms when they need to use them. Condom social marketing (CSM) programs have succeeded in increasing the use of condoms in many countries. Condom program activities are therefore essential components of public health approaches to HIV and other STI prevention and control. These activities include: educating people about the need for condom use (demand creation); ensuring condom availability (supply activities); and providing support for condom use and condom programs.

4.8.2. Strategies

The following strategies will be implemented in collaboration with relevant stakeholders where applicable

- Condom promotion should be undertaken in all clinics that offer STI services, including specialized STI clinics; maternal and child health and family planning (MCH/FP) services; outpatient departments; and at primary health care services. All patients that have been diagnosed with a STI should:
    - be counseled about the importance of condoms in preventing STI;
    - be shown how to use a condom correctly;
    - leave the clinic with some condoms, in case they have sexual intercourse
    - be told where they can be given regular supplies of condoms
- Condom promotion should be undertaken in all workplace settings:
    - Establish a mechanism that enable workplace settings to access condoms and promotion materials
    - Workplace settings are to be registered as primary or secondary distribution sites based on the number of employees or volumes of condoms they can use as per the relevant SOP
- Put in place a system that enable condoms programs managers to identify new and existing laws and legislation which may restrict condom promotion and distribution activities and advocate for them to be revised them with the help of relevant people and sectors
- Public promotion of condoms can be implemented at primary healthcare facilities and secondary distribution sites by maintaining and displaying useful and attractive information such as posters, charts on the walls, leaflets and brochures to in hand-out baskets, as well as videotapes to showing (where equipment is available) key messages or relevant plays
- Through relevant NGOs, CBOs, and FBOs, high-risk groups can also be targeted in the community, through HIV/STI prevention activities, such as outreach programs, visits by local community health

workers, and home based-care

- Design a sexual health information package for young people aged 14 years and older
- Develop and implement condom communication or advocacy strategy
- Develop tailor- made condom information, education and communication (IEC) materials for high risk groups as defined in the NSP 2007-2011, particularly the youth, commercial sex workers (CSW's), long distance drivers, refugees,…etc
- Conduct regular condom awareness campaigns (print media, national and local/community radio stations) to address myths and misconceptions hampering condom use
- Develop and strengthen partnership with identified stakeholder's e.g. church leaders, traditional leaders, and encourage them to become advocates for condom use
- Healthcare professionals and other service providers must have the appropriate knowledge, attitudes and skills to carry out condom promotion activities. Training should target all health workers dealing with patients suffering from STI or simply consulting for reproductive health or other conditions.
    - In order to enhance the knowledge and skills of service providers in condom promotion, the following steps should be considered:
        - integrating condom promotion into the basic training and refresher training of health professionals;
        - producing practical guidelines and self-learning materials;
        - including condom promotion in the management protocols that are usually issued by the Ministry of Health
    - The objectives of the training should cover three main areas: knowledge, attitudes and skills.
        - Knowledge: The technical knowledge of service providers related to condoms should be improved through such means as becoming familiar with the characteristics of condoms and the various brand types available; learning about specific policies regarding condom availability and distribution; learning about the common obstacles to condom promotion and use; learning how condoms should be used and disposed of; learning about NDOH policies with regard to condoms and other reproductive health issues
        - Attitudes: The attitudes of service providers with regard to condom effectiveness and use should be improved through them acquiring an understanding of social norms and attitudes in general, enabling service providers to respond to clients' concerns about condoms. And acquiring an understanding of how age, gender, educational level, social class, beliefs, values, income level, sexual behaviours and preferences may affect practices and attitudes towards condoms.
        - Skills: STI service providers should be equipped with the appropriate skills to enable them to communicate effectively with clients and counsel them on condom use issues ; manage supplies of condoms at facilities, including checking their validity and identifying stock needs; and monitor and report on the utilization of condoms by clients and keep track of problems and constraints
    - Design a relevant curriculum and conduct the training for Peer Educators (youth, CSW's, MSM, men and women sector) and Community Health Workers (CHW's) as well as staff working at condoms distribution sites. It is expected these people should have the knowledge of:
        - Condoms and their efficacy in pregnancy and STI prevention
        - STIs, HIV and Teenage pregnancy
        - How to use condoms and lubricants

- Basic Sexual Health Promotion
- Basic counseling skills

4.9. Monitoring and evaluation of condoms program activities

4.9.1. Objective: To ensure the monitoring and evaluation of condoms logistics management program activities

The STI-HIV Prevention Unit runs the Condom Procurement and Distribution Program as well as the related promotional activities. These activities will be considered successful if they lead to increased awareness and continued use of condoms, and uninterrupted availability of condoms when clients need them. Hence, the monitoring and evaluation of activities are very important.

The purpose is to improve and correct what is being done from forecasting to condom promotion and distribution. The Logistics Management Information System (LMIS) based at NDOH serves as a database of all condom transactions to PDS's and should provide the data needed for planning the replenishment of condoms.

The STI-HIV Prevention Unit as the focal institution designated to coordinate condom programming activities will be responsible for managing monitoring and evaluation activities through the logistics officer. Given the limitation of resources, including funds, and the limited time that health staff usually have available, the national managers of condoms activities need to be selective in what they wish to monitor and evaluate in terms of progress and impact.

With regard to progress indicators, it is important to monitor:

- Reporting rates: Percentage of facilities that submitted a report during a designated reporting period
- Average lead times: On average, the time it takes from when a facility places a report/order to when the goods are received and available for use
- Stock-out rates: Percentage of facilities experiencing a stock-out
- On-time delivery rates: Percentage of facilities receiving a delivery as scheduled
- Order fulfillment rate: Percentage of facilities that had their complete order filled by the supplying facility
- What are the quantities of condoms distributed to and by PDSs and SDSs and other facilities or services, and how many condoms have been received as donations and from whom;
- Percentage of wasted condoms= quantities counted - quantities unusable (expiration or damage) x 100
- Percentage Difference between Consumption Forecasts and Actual Consumption

On the other hand, there are impact indicators, which are needed to determine the effect of condom promotion and use on the HIV and other STI situation, including clients' practices. These include the reported condom use percentage: what clients report on their use of condoms, including whether this use is consistent and continuous; the incidence of HIV and sexually transmitted infections among high-risk groups, STI clients, and the general population.

4.9.2. Strategies

- Appoint a staff member dedicated to the M&E function so that s/he can conduct regular meetings with PDS personnel to address challenges, constraints and share successes
- Develop a yearly M& E plan to be implemented by the M&E personnel
- Monitor on a quarterly basis the targets set in the Condoms Supply and Distribution plan

- Conduct periodic evaluations of the supply chain in order to assess the system's strengths and weaknesses, and opportunities for interventions.
    - The purpose and scope of the evaluation will determine whether the assessment should be primarily quantitative or qualitative
    - The purpose of conducting an evaluation, in addition to the ongoing monitoring of the system, is the ability to calculate different and broader indicators to measure performance such as indicators relating to acceptable storage conditions, accuracy or logistics recordkeeping, and stock-outs on the day of visit
- Encourage and ensure that PDS and SDS send regularly their monthly consumption reports to the officials at the NDOH
- Ensure that relevant condoms program activities and services data are captured in a standardized manner in all provinces:
    - Produce and distribute standardized forms to provinces and SDPs
    - Institute a reporting mechanism based on the relevant SOP
    - Appoint dedicated personnel responsible for data capturing

4.10. Research on condoms issues

4.10.1. Objective: To ensure relevant operational research is conducted to inform policy and practices

Relevant research findings could usefully inform the process of policy/legislation revision regarding, for instance, the minimum age for minors to give consent for contraception without parental assistance. They also could be used for responsive program planning, such as to address identified gaps in service provision for adolescents and high-risk groups. Condom consumption rate is an important indicator that needs to be established in order to estimate the wastage in the condoms distribution system.

4.10.2. Strategies

- Make budgetary provisions to commission research on condoms
- Develop a condoms research agenda and conduct annual surveys on identified issues such as
    - Condoms availability in retail outlets and PDS and SDSs: in order to determine the proportion of randomly selected retail outlets and service delivery points that have condoms in stock at the time of a survey, of all retail outlets and service delivery points (SDP) selected for survey
    - Condoms quality at SDPs: The quality of condoms at their time of use determines their effectiveness in preventing HIV, STIs and pregnancy. It is important to know the percentage of condoms in central stock and in retail outlets that meet quality specifications
- Contract research staff and monitor their performance
- Use the research findings to inform decision-making, policy review, and changes in current practices
        - Provide policy-makers with the results of research showing HIV and other STI prevalence, and illustrate the cost-effectiveness of promoting female and male condoms
        - Provide journalists with data from local or national research proving the reliability of condoms, and refer to studies which prove that HIV, STI, and sperm cannot pass through a latex (rubber) condom
        - Hold seminars (or include briefings in training programs) for health workers, school managers, community workers to make them aware of findings from nationally-funded research results on condoms issues
- Develop a database of published papers on condoms issues relevant to South Africa
- Develop the research management capacity of staff involved in the management of condoms at national and provincial levels

5. APPENDIXES

Appendix 1: Condom Demonstration Guidelines

The facility should have the condom demonstrator tools and condoms. Demonstrations can be done during the drop-in timings with every client that came for their first consultation or for a groups during promotion activities or in a class.

Overall guidelines for condom demonstration will be:

• Try to do at least one condom demonstration with each young person, individually or in groups, involving the young person(s) in that process.

• When condoms are given out to young people, it should be a pre-requisite to do the condom demonstration whenever practically feasible. Condom demonstration increases the young person's skills so that they can avoid or know what to do in case of breakages, slippages, or other damages.

These guidelines are intended to be flexible, according to the client's needs:

• A condom demonstration should be shown to all first time clients and /or if the young person has informed the staff member that they had a condom split while in use

• Ensure that the area for distribution is private where the conversation is not likely to be overheard.

• If possible, give the young person the choice of consultation with male or female worker.

• Be friendly and welcoming to put the person at ease.

• Outline service confidentiality policy

• Explain the different types of condoms that are available and what their recommended use is, including oral sex.

• Discuss condom storage and implications if others find them

• Discuss what to do if a condom splits during sex and ensure that the client knows about EC (emergency contraception) and how and where to access it.

• Issues to cover

- Show quality assurance mark : "SABS sign" and expiry date

- Be careful if using jewellery

- How to open the packaging

- Squeezing the teat, to exclude air until condom is fully unrolled

- Make sure condom is not inside out and is rolled down to the base of the demonstrator tool

- Provide information about appropriate water based lubricants

- Emphasize that "Put the condom on before sexual contact"

-Emphasize "Withdraw before penis goes soft" while holding the base of condom so semen does not leak out

- Demonstrate how to check for splits, leaks

- Demonstrate the disposal- Wrap condom in tissue and put in bin, do not flush down the Toilet

- Emphasize "Use another condom for further penetrative sexual act

Appendix 2: Female condom specifications

1. GENERAL REQUIREMENTS

Manufacturers and Suppliers shall follow an appropriate code of quality management, including good quality management system as required in the manufacture and packaging of condoms. Female condoms should be designed and produced in accordance with a good quality management system and ISO 14971-1 and ISO13485

A female condom shall be retained in the vagina after insertion and shall completely line the vaginal canal. Female condoms shall be free from holes and defects, have adequate physical properties so as not to break during use, be correctly packaged to protect them during storage, and correctly labeled to facilitate their use.

The lubricant applied to female condom shall not contain or liberate any substances in amounts that are toxic, sensitizing, locally irritating or otherwise harmful under normal conditions of storage and use.

Manufacturers shall conduct stability tests to ensure adequate data to support shelf life claims. The data should be made available for review by regulatory authorities, third party test laboratories and purchasers.

A practicable method for assessing conformity is by testing a representative sample from a lot or series of lots. Basic sampling plans shall be in accordance with ISO 2859-1.It is necessary to know the lot size in order to obtain the number of female condoms to be tested

To assess the safety and effectiveness of a new female condom design; a contraceptive effectiveness study shall be conducted in accordance with ISO14155.

International Standards Organisation Technical Committee ISO/TC 157 is developing an International standard for female condoms. From the information gathered and recommendations cited by a team of internationally recognised technical experts and advisors, the Female Condom Technical Review Committee was established by WHO/RHR in January 2006 to conduct the female condom review

New female condoms designs that are sufficiently similar to a design that is already approved and marketed may claim exemption from the clinical investigation requirements

Unless specifically indicated otherwise, all statistical sampling plans and acceptable quality level (AQL) values listed and referred to in this specification shall be in accordance with ISO 2859-1.

The methods used to test for compliance are:

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

2. CONSTITUENT MATERIALS

- The condoms shall be made from a synthetic latex made from nitrile material (**terpolymer of butadiene, acrylonitrile and methacryllic**)
- The material shall be free of embedded solid impurities and discoloration.
- Female condoms shall not liberate toxic or otherwise harmful substances under normal conditions of use.
- The compounding materials used (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. The use and type of accelerators shall be stated. Excess accelerators and other leachable chemicals shall not be used.
- Careful attention shall be given in the formulation to suitable antioxidants in order to provide maximum protection under adverse storage conditions.
- Biocompatibility (in accordance with ISO 10993) tests results appropriate for a medical device in contact with non-intact breeched mucosal surfaces for extended periods shall be presented.
- Data from type testing for viral permeability shall be presented

These requirements will be verified by documentary evidence.

3. DESIGN

3.1 The female condom shall be designed to prevent pregnancy and/or sexually transmitted infections during vaginal intercourse. The female condom is distinguished from a male condom in that it is retained in the vagina after insertion before sexual intercourse.

3.2. Product Insertion Feature

The insertion feature of a female condom design shall comply with the requirements in clause 5.2 of ISO/DIS 25841 (2007-05-04) Design for female condoms shall include either a feature or a tool to aid in the proper insertion and deployment of the female condom.

The insertion feature design, material and/or method shall be evaluated for function as part of the design validation and clinical evaluation of the finished female condom device.

The insertion feature material will be evaluated for biocompatibility as an integrated feature of the finished female condom device in accordance with ISO 10993.

3.3. RETENTION FEATURES

The retention feature of a female condom design shall comply with the requirements in clause 5.3 of ISO/DIS 25841(2007-05-040).

Designs for female condoms shall incorporate intra vaginal retention features to retain the female condom within the vagina during sexual intercourse and permit safe withdrawal after use.

Designs for female condom shall incorporate external retention features to keep the open end of the female condom open during sexual intercourse and to prevent misdirection of the penis, female condom invagination and slippage.

The external retention features shall include but not limited to annular, triangular or other shaped components affixed to the open end of the female condom

Retention feature materials shall be evaluated for biocompatibility as an integrated feature of the finished female condom device in accordance with ISO 10993.

1.4 LUBRICATION

The design of a female condom shall include lubrication pre-applied directly on the packaged condom. The range for the mass of lubricant shall be specified by the manufacturer based on the amount of lubricant used in the clinical trial.

When tested in accordance with the method given in Annex C of ISO/DIS 25841(2007-05-04) taking 13 female condoms per lot, the mass of lubricant mass measurement shall not exceed the manufacturer's specified range.

3.5 DIMENSIONS

3.5.1. Length

The range of the length of the female condom shall be specified by the manufacturer based on the female condoms used in the clinical trial.

When tested in accordance with the method given in Annex D of ISO/DIS 25841(2007-05-04), taking 13 female condoms per lot, the length measurement shall not exceed the manufacturer's specified range.

1.1.2 Width

The range of the width of the female condom shall be specified by the manufacturer based on the female condoms used in the clinical trial.

When tested in accordance with the method given in Annex E of ISO/DIS 25841(2007-05-04) taking 13 female condoms per lot, the width measurement shall not exceed the manufacturer's specified range.

3.5.3. Thickness

The range of the thickness of the female condom shall be specified by the manufacturer based on the female condoms used in the clinical trial

When tested in accordance with the method given in Annex F of ISO/DIS 25841(2007-05-04) taking 13 female condoms per lot, the female condom thickness measurement shall not exceed the manufacturer's specified range.

3.6 Risk assessment

A risk assessment for the product shall be conducted in accordance with ISO14972-2. The assessment shall identify potential failure modes for the device as well as any other safety and efficacy concerns.

Manufacturers shall make available the results of the risk assessment for the design as described in annexure G of ISO/DIS 25841(2007-05-04)

PERFORMANCE REQUIREMENT

4.1 Air burst properties

The minimum values for burst pressure and volume shall be based on a definite requirement such as the 0.75% as described in ISO/DIS 25841(2007-05-04) paragraph 9.1.

When tested in accordance with the method given in Annexure I of ISO/DIS 25841(2007-0504) taking 13 female condoms per lot, the burst pressure and volume shall not be outside the manufacturer's specified range.

4.1.1 Minimum value

The minimum bursting volumes and bursting pressures shall be established in accordance with clause 9.1 of ISO/DIS 25841(2007-05-04).

4.1.2 Sampling and requirements

When tested in accordance with the method in ISO/DIS 25841(2007-05-04) the burst volumes and burst pressures shall not be less than the minimum values established by the procedures described in 9.1of the International Standard.

General Inspection Level I of ISO 2859-1 shall be used for a continuing series of lots.

5. Test for Stability requirements

5.1 General

Manufacturers shall verify that the female condom conform with the airburst, freedom from holes, visible defects and labeling requirements given in clauses 9, 11, 12, and 13 of the ISO/DIS 25841(2007-05-04) until the end of the labeled shelf life. Shelf life claims shall not exceed five years.

5.2 Minimum stability requirements

Three lots of female condoms shall be tested for conformity prior to stability testing for conformity with clauses 9, 11, 12, and 13 of ISO/DIS 25841(2007-05-04) using the sampling plans given in Annexure B

5.3 Procedure for determining shelf life by real time stability studies

After testing in accordance with Annexure K female condoms shall comply with the requirements given in

clause 9, 11, 12 and 13 of ISO/DIS 25841(2007-05-04).

The NDOH shall be notified if the real time data indicate a shorter shelf life than that claimed on the basis of the accelerated test study. The manufacturer shall change the shelf life claim to the one based on the real time study.

5.4 Estimating shelf life based on accelerated stability studies

Shelf life estimates for accelerated stability studies shall be based on a mean kinetic temperature of 30°C. The manufacturer may use the method described in Annexure L of the ISO/DIS 25841(2007-05-04) to conduct accelerated stability studies.

6. Freedom from Holes

Female condoms shall be tested for freedom from holes in accordance with the requirements and clause 11 of ISO/DIS 25841 (2007-05-04).

7. Visible defects

Female condoms shall be tested for visible defects as described in Annexure M of ISO/DIS 25841(2007-0504). The AQL and inspection level established in Annexures A and B shall apply.

8. Packaging and labeling

1.1 Package Integrity

Individual female condom packages shall be tested for package integrity in accordance with clause 13.1 of ISO/DIS 25841(2007-05-04) The AQL shall be 2.5.

1.2 Packaging

Each female condom shall be packed in an individual sealed container unit flow wrap sachet with top tear notch. The lot number, expiry date, the words "Department of Health South Africa" and "NOT FOR SALE" shall be printed at the time of packaging.

100 sachets shall be packed into a box, and 5 boxes shall be packed into a shipping carton..

1.3 Labeling

1.3.1 Individual containers

Each individual container shall be marked with the following information:

a) The identity of the manufacturer
b) The manufacturer identifying reference for traceability
c) The expiry date (year and month)

8.3.2 Consumer packages

1.1.1.1 General

The outside of the consumer package shall bear at least the following information:

a) Description of the female condom
b) The expiry date (year and month)
c) A statement of appropriate storage conditions for the female condom material
d) The manufacturer's identifying reference for traceability
e) A statement indicating the type of female condom material

1.1.1.2 Additional information for the consumer

The outside of the consumer package, or leaflet contained within the consumer package, shall bear at least the following information, expressed in simple terms and in at least one of the official languages and/or pictorial representations of the major steps involved

a) instructions for use of female condom and
b) a statement that the female condom is for single use only
c) instruction for disposal

8.4 Inspection

13 consumer packages and 13 individual containers shall be selected from each lot and examined for conformity with clause 13.1, 13.2 and 13.3 of ISO/DIS 25841(2007-05-04).

Appendix 3: Male condom specifications

1. GENERAL REQUIREMENTS

Manufacturers and Suppliers shall follow an appropriate code of quality management, including good manufacturing practices (GMP) as required by the South African Bureau of Standards (SABS) Mark Scheme and statistical process control, in the manufacture and packaging of condoms.

The methods used to test for compliance are:

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

Requirements marked with a star/* will be tested on each lot and will be seen as critical to the fulfilment of the tender agreement. The remaining requirements will be tested on a random basis. Should any of the condoms not meet the requirements when tested that particular lot will be considered to be unfit for delivery and therefore in €€breach of the tender agreement and will be subject to the conditions held therein.

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 in amounts that can be irritating, sensitising or otherwise harmful to the user of the condom under normal conditions of use.
- 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. The use and type of accelerators used should be stated. Excess accelerators and other leachable chemicals should be avoided.
- Careful attention shall be given in the formulation to suitable antioxidants in order to provide maximum protection under adverse storage conditions.
- All materials must comply strictly with the requirements of the applicable portions of the US Code of Federal Regulations (USCFR) 21 and/or latest updated version.

These requirements will be verified by documentary evidence.

1.2 Shelf-life

Condoms shall comply with the performance requirements of this specification throughout the stated shelf life of the condom.

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^{0}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 5 years. At the time of delivery at least 80% of the shelf-life must still be available to the procurer.

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

1. Real time stability studies conducted over the stated shelf-life at 35^{o}C

2. 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,

3. 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.

Updated documentation on 35^{0}C post-market trials must be made available to the purchaser on request. *Validated expiry dates up to 5 years will be allowed.*

1.3 Resistance to oxidation (independent of the package)

(i) Sampling

One hundred (100) condoms per lot

(ii) Testing

Remove the condoms from their packages. Place the rolled condoms in an oven at 70 $\pm$ 2^0 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.

(iii) 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.

Talc and lycopodium spores shall not be used.

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

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^{0}C at maximum humidity for the stated shelf-life.

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*

(i) 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 vulcanisation errors.)

(ii) Testing

In accordance with the inflation test and oven conditioning procedure in *ISO 4074, Annexure G* and the relevant clause in *ISO 4074*.

(iii) 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 1kPa. The minimum volume is arrived at by the following formula:

$$\text{minimum limit (litres)} = \frac{w^2}{150} \quad \text{(rounded off to the nearest 0.5 litres)}$$

The width 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 determined in accordance with ISO 4074.

After oven conditioning, neither the mean bursting pressure nor the mean bursting volume shall diminish by more than 20%.

2.2 Freedom from holes*

(i) Sampling

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

(ii) Testing

The test is carried out in accordance with *ISO 4074, Annexure L*.

Condoms breaking or tearing as a result of prescribed handling will be considered failures.

(iii) Requirement

AQL 0.25.

2.3 Package integrity*

(i) Sampling

ISO 2859-1 Special Inspection Level S-3.

(ii) Testing

In accordance with Package Integrity Test Method in *ISO 4074* Annex M

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 $\pm$ 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.

(iii) Requirement

AQL 2.5%

3 DESIGN REQUIREMENTS

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 statistical samples and prescribed test protocols.

Tests or verifications in this section will generally be:

- at the pre-qualification[1] 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 other than the mandatory lot by lot testing 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).

1 Pre-qualification is the process, which proceeds the tender during which the supplier provides condoms for testing and other appropriate documentation according to the requirements of this specification to gain entry in to the tender.

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 rolled ring of latex, called an integral 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 manufacture and for the shelf life of the product. (Condoms have a characteristic odour of rubber, which tends to dissipate quickly once the package is opened)

The manufacturer or the manufacturer's agent will store 100 condoms for at least one year at room temperature from each certified lot[2] for use in resolving disputes regarding odour.

The condoms shall be free from taste**.**

3.1 – 3.4 verify by visual and other appropriate inspection methods

3.5 Length*

(i) Sampling

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

(ii) Testing

According to the length measurement procedure in *ISO 4074 Annexure D*

(iii) Requirement

A minimum of 180 mm allowed.

3.6 Width*

(i) Sampling

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

(ii) Testing

According to the width measurement procedure in *ISO 4074 Annexure E*

2 A certified lot is a lot of condoms, which has been tested and found to meet the requirements in this specification by the procurer's testing agents.

(iii) Requirement

A width of 53 mm with a tolerance of ± 2 mm is allowed for individual condoms with an AQL of 1.0% and in addition a tolerance of ± 1 mm for the mean of the lot.

3.7 Thickness*

(i) Sampling

ISO 2859-1 Special Inspection Level S-2.

(ii) Testing

In accordance with test method in ISO 4074 annex F

The measurement of thickness is done with a micrometer mounted on an anvil, with 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.

(iii) 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 *

(i) Sampling

ISO 2859-1 Special Inspection Level S-2.

(ii) Testing

In accordance with test method in *ISO 4074, Annex C*

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 milligram (mg).

The weight 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.

(iii) Requirement

The quantity of silicone lubricant, including powder, in the package shall be 550 ± 150 mg. With an AQL of 4.0%. The viscosity of the silicone lubricant shall be between 200 and 350 centistokes at manufacture.

3.9 Individual package materials and markings*

(i) Sampling

ISO 2859- Special Inspection Level S-3.

(ii) Testing

The sample of condom packages is visually inspected to verify the required aspects of package quality.

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.
- The outside surface of the package shall be clean.
- There shall be no separation of the layers of laminate.
- Sealed packages are in strips of up to 4, 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 will have a notch or serration to assist in opening.
- The packages shall have the following ***indelible*** markings:
  - Manufacturer's name
  - lot or lot identification code (printed at the time of packaging, not pre-printed);
  - Manufacturing date: Month and year- labelled Manufacturing Date
  - *Expiry Date: month and year of expiry labelled **in full** or **Exp Date abbreviated*** in English (the year shall be written as a four digit number, and the month as a two digit number);

    Requirement

    AQL 2.5%.
    Verify by visual inspection

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, lot-by-lot compliance testing and during periodic inspections/ audits.

4.1 Cartons and markings

(i) 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.

(ii) Testing

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

(iii) Requirements

The individual requirements for the various packaging materials 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 following table:

Classification of defects in packaging and marking of packages for delivery

Examine Defects *Contents* Number of condoms not as specified; packages or strips not as specified.

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

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

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

Exterior Shipping Cartons

Thirty dispenser boxes will be packed into plastic waterproof lining bags, which will be placed into three-wall corrugated fibreboard cartons (in three layers of ten dispenser boxes each) made from weather-resistant fibreboard with a bursting 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.

The exterior shipping carton, like the bulk carton, shall be marked on the exposed face with information about the contents in a clearly legible manner. The information shall include:

- Lot or lot identification number
- Month and year of manufacture (including the words *Date of Manufacture, Month, Year)* in English. 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 English. The year shall be written as a four-digit number, and the month as a two-digit number
- Name and address of contractor
- 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.

Each LOT or LOT identification code shall start with the suppliers four digit SABS mark holder registration number followed by a three letter contractor identifier, followed by a unique lot number e.g. 1234/ABC/030001.

5.0 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 (9 days) - P (2days) < 25%**	
PERFORMANCE REQUIREMENTS	**2**				
Bursting volume	**2.1**	**G-1***	**ISO 4074 see Specification 2.1**	**width²/150**	**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 see Specification 2.2**	**<3 holes**	**0.25**
Package integrity	**2.3**	**S-3***	**see Specification 2.3**	**<3 leaks**	**2.5**
DESIGN REQUIREMENT	**3**				
Length	**3.5**	**S-2***	**ISO 4074**	**>=180 mm**	**1.0**
Width	**3.6**	**S-2***	**ISO 4074**	**53 ± 2 mm; mean 52 ± 1 mm**	**1.0**
Thickness	**3.7**	**S-2***	**see Specification 3.7**	**0.065 ± 0.015 mm**	**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***	**see Specification 3.9 Specification 4.1**	**Visual Inspection**	**2.5**

South Africa National Department of Health
P/Bag X828
Pretoria 0001

Tel +27 (0) 12 395 8000 http://www.doh.gov.za