World Health Organization

DRAFT WORKING DOCUMENT FOR COMMENTS:

World Health Organization/United Nations Population Guidance on testing of male latex condoms

Please send your comments to **Dr Sabine Kopp**, Team Lead, Norms and Standards for Pharmaceuticals, Technical Standards and Specifications (kopps@who.int), with a copy to Ms Claire Vogel (vogelc@who.int) before **20 August 2020**. Please use our attached Comments Table for this purpose.

Our working documents are sent out electronically and they will also be placed on the WHO Medicines website (http://www.who.int/medicines/areas/quality_safety/quality_assurance/guidelines/en/) for comments under the "*Current projects*" link. If you wish to receive all our draft guidelines, please send your email address to jonessi@who.int and your name will be added to our electronic mailing list.

SCHEDULE FOR DRAFT WORKING DOCUMENT QAS/19.805/Rev.1:

World Health Organization/United Nations Population Fund Guidance on male latex condoms

Description of activity	Date
The United Nations Population Fund (UNFPA) identified the need to update the existing *Procedure for assessing the acceptability, in principle, of male latex condoms for purchase by United Nations agencies*, adopted by the Forty-second WHO Expert Committee on Specifications for Pharmaceutical Preparations (ECSPP) meeting and published as Annex 2 in the WHO Technical Reports Series, No. 948, 2008. The text had been developed by the UNFPA and WHO specialists.	
Informal discussions amongst UNFPA and WHO specialists on the management of this updating process.	May – September 2018
Presentation of a possible updating process of the prequalification guidance for contraceptive devices and condoms at the Fifty-third ECSPP.	18 October 2018
Following the recommendation of the Fifty-third ECSPP meeting, various phases of reworking and restructuring of the specific texts by UNFPA.	November 2018 – May 2019
Mailing of working document for public consultation, including to the WHO Expert Advisory Panel on the International Pharmacopoeia and Pharmaceutical Preparations (EAP) and UNFPA specialists, inviting comments and posting of the working document on the WHO website.	Mid-July 2019
Compilation of comments received by WHO.	September 2019

Review of comments received by a group of specialists. Preparation of discussion document.	October 2019
Presentation to the Fifty-fourth ECSPP in Geneva, Switzerland.	14-18 October 2019
Review of comments received by a group of specialists. Preparation of discussion document.	October 2019-May 2020
Mailing of working document for public consultation, including to the EAP and UNFPA specialists, inviting comments and posting of the working document on the WHO website.	May 2020
Compilation of comments received by WHO.	August 2020
Review of comments received by a group of specialists. Preparation of discussion document.	September 2020
Presentation to the Fifty-fifth ECSPP in Geneva, Switzerland.	12-16 October 2020
Further follow-up action as required.	

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World Health Organization/United Nations Population Fund Guidance on testing of male latex condoms

Background

The report of the Fifty-fourth meeting of the World Health Organization (WHO) Expert Committee on Specifications for Pharmaceutical Preparations (ECSPP) in 2019 (*1*)) stated the following:

> *As agreed at the ECSPP meeting in October 2018, the United Nations Population Fund (UNFPA) and WHO have separated out different aspects of the current procedure for contraceptive devices and condoms and are developing seven different documents:*
>
> - *prequalification programme guidance for contraceptive devices: male latex condoms, female condoms and intrauterine devices;*
> - *technical specifications for male latex condoms;*
> - *specifications for plain lubricants;*
> - *condom quality assurance;*
> - *guidance on testing of male latex condoms;*
> - *recommendations for condom storage and shipping temperatures; and*
> - *guidance on conducting post-market surveillance of condoms.*
>
> *All seven documents were restructured and revised in the first half of 2019, then sent to the EAP and put out for public consultation in July 2019. The comments received were reviewed by a group of specialists in October 2019, prior to being presented to the ECSPP. At UNFPA's request, the ECSPP focused on the first three documents (on UNFPA's Prequalification Programme guidance, condom quality assurance and specifications for plain lubricants), noting that all comments have been addressed. It suggested some further minor revisions, including recommending changes to clarify that, while the specifications for plain lubricants are principally targeted at procurement agencies, they may also be used by regulators for*

public procurement. The next steps for the remaining four documents include incorporating comments from the latest consultations and then bringing them back to the ECSPP for possible adoption at its next meeting in 2020.

The Expert Committee adopted the following guidelines:

- *World Health Organization/United Nations Population Fund Prequalification Programme guidance for contraceptive devices: male latex condoms, female condoms and intrauterine devices (2);*
- *World Health Organization/United Nations Population Fund technical specifications for male latex condoms (3); and*
- *World Health Organization/United Nations Population Fund specifications for plain lubricants (4).*

The Expert Committee further recommended proceeding with the next steps as discussed.

This is one of the four remaining working documents in this series.

1. Introduction
2. Determination of length (*ISO 4074:2015*, Annex D)
3. Determination of width (*ISO 4074:2015*, Annex E)
4. Determination of thickness (*ISO 4074:2015*, Annex F)
   - 4.1 Mass method
   - 4.2 Micrometer method
5. Determination of bursting volume and pressure (*ISO 4074:2015*, Annex H)
   - 5.1 Loading of the condom onto the mandrel
   - 5.2 Ensuring the correct inflation length
   - 5.3 Checking that the condom does not slip during inflation
   - 5.4 Calibrating the volume and pressure measuring equipment
   - 5.5 Correcting for variations in atmospheric pressure owing to the altitude of the test laboratory
   - 5.6 Other factors to consider in the burst testing of condoms
6. Determination of stability and shelf-life (*ISO 4074:2015*, Annexes K and L)
7. Freedom from holes

1. Introduction

Condoms, procured as part of a public procurement programme or otherwise, are tested as per the World Health Organization (WHO)/United Nations Fund Population (UNFPA) specification by independent laboratories. In addition, there may be specific programme requirements which would have been incorporated in the purchase orders. These testing laboratories have to be accredited to *ISO 17025:2017, General requirements for the competence of testing and calibration laboratories* (*5*), for the test methods in *ISO 4074:2015, National rubber latex male condoms – Requirements and test methods* (*6*), in order to be considered for testing services. The following guidance has been developed to assist the laboratories to standardize testing and reduce variability. This guidance is meant to supplement the information on conducting the tests specified in *ISO 4074:2015* (*6*).

2. Determination of length (*ISO 4074:2015*, Annex D)

Condom length can be measured manually, using a suitable calibrated mandrel, or automatically, using one of the instrumented machines now available.

The automatic methods have the advantage that data can usually be transferred directly to any computerised record system, although it is important that the equipment is validated for the correct handling of the data and regularly calibrated following the methods recommended by the manufacturer.

A standard mandrel, described in *ISO 4074:2015* (*6*), is used to normalise the measurements as different condom designs can have different shapes at the teat and closed end.

As a rolled condom can retain the memory of the roll when unrolled, it is permitted to stretch the condom a little (no more than 20 mm, and no more than twice) when unrolled to help remove any wrinkles persisting after the unrolling.

Condoms can be measured without removing the lubricant but handling a lubricated condom can be difficult as the lubricant can cause the condom to stick to itself in pleats or creases. A lubricated

condom may also not hang freely over the mandrel and, if stretched, can be held in the extended state by the lubricant. The condom can be powdered to ease the handling problems, as described in the standard, with or without removal of the lubricant.

Owing to the way the bead is formed, the condom length may not be exactly the same at all points around the condom. It is important to measure the length at several points and record the minimum. The instrumental methods may do this automatically.

When measuring the length manually, it is important that the measurement is taken with the bead of the condom at eye level to avoid any parallax errors. It may be easier to position the mandrel on a stand to bring it up to the eye level of the operator. Again, the instrumented methods will take this into account. While fixing the length mandrel, it should be ensured that it is fixed on a horizontal plane without slanting.

Note that the condom length should be measured to the nearest 1 mm.

3. Determination of width (*ISO 4074:2015*, Annex E)

Condom width can be measured directly, using a ruler, or automatically using one of the automated machines now available.

The automatic methods have the advantage that data can usually be transferred directly to any computerised record system, although it is important that the equipment is validated for correct handling of the data and regularly calibrated following the methods recommended by the manufacturer.

When measuring directly, using a ruler calibrated in mm, it is important that the condom is positioned so that the axis of the condom is exactly perpendicular to the ruler.

Note that the end of a ruler can get worn and the corners rounded so it is better to position the condom to use another point (e.g. the 10, 20 or 100 mm index) as the zero. The condom should be measured at the narrowest point within the range 20 to 50 mm from the open end.

Condoms can be measured without removing the lubricant but handling a lubricated condom can be difficult as the lubricant can cause the condom to stick to itself in pleats or creases. Gently manipulate the condom to smooth out any such creases, ensuring that the condom is not stretched as sometimes the lubricant can hold the condom in an extended state. It may be better to remove the lubricant and lightly powder the condom, especially if the same condoms will be used for the determination of length.

Note that the condom width should be measured to the nearest 0.5 mm which will require the measurement to be interpolated if the scale is in whole mm.

4. Determination of thickness (*ISO 4074:2015*, Annex F)

ISO 4074:2015 (*6*) allows two methods for the measurement of thickness, one based on the direct measurement by a micrometer, and the other by mass. The mass method was introduced owing to the fact that the precision and reproducibility of the micrometer method was found to be relatively poor. One of the reasons for this is to accommodate condoms where the surface is not smooth and, also, it is thought that the pressure applied by the foot of the micrometer to ensure good contact with the material under test can compress the film slightly. In some cases, this pressure has also been found to be well outside the specified range.

Any lubricant on the condom is removed by washing or wiping the condom with propan-2-ol, and removing the lubricant can make the condom difficult to handle. If any powder is added to facilitate handling and sample preparation, this must be removed before measuring.

The thickness of a condom can vary along and around the condom and, for this reason, thickness is measured at three points on the condom: the mid-point (± 5 mm) of the condom, 30 ± 5 mm from the closed end and 30 ± 5 mm from the open end. If the micrometer method is used, then three measurements, approximately equally spaced around the condom, are taken at each location and averaged. The mass method, of course, will give the average thickness of the sample being measured. For textured condoms, the thickness is usually measured using micrometer method at the point specified and agreed between the manufacturer and the buyer of the condoms.

4.1 Mass method

The mass method calculates the volume of the sample by dividing the mass of the sample by the density of natural rubber. If the length and width of the sample are known, then the thickness can be simply calculated.

The formula, as given in Annex F of *ISO 4074:2015*, is:

Thickness (in mm.) = $\frac{1}{0.92} \times \frac{1}{A} \times m$

using a density of 0.92 g/cm^3, and where A is the area of the test piece (length in mm. x 20) in mm^2 and *m* is the mass of the sample in mg. If the condom is not parallel-sided, then measure both of the long sides and use the average.

The method specifies the test piece for tensile testing as the sample. This has the advantage that many laboratories already have the cutting die to give a 20 mm wide ring test piece from a condom.

Whilst there will be very slight differences in the density of the condom, caused by differences in the formulations, these will not cause any significant changes in the calculated thickness.

4.2 Micrometer method

The micrometer method measures the thickness of the sample directly using a calibrated dial or digital micrometer capable of reading to the nearest 0.001 mm. If the condom is textured, then micrometer measurements on the textured portion can give false results. In this case, measure the condom at a non-textured region as close as possible to the specified points (and report this with the results). Alternatively, the mass method could be used. Zero the gauge after measuring each sample.

Because of the compressibility of rubber, it is essential that the foot pressure is within the specified 22 ± 5 kPa and measuring the foot pressure should form part of the regular calibration

procedure for the gauge. Note that powder or lubricant on the shaft of the gauge may increase friction when the gauge is used, altering the foot pressure. For this reason, it is important to ensure that the gauge is kept clean.

It is essential that the foot of the micrometer is exactly parallel to the platen. If not, then the edge of the foot, rather than the face, will contact the sample. Under the defined load, the edge can dig into the sample and give a false reading. A photograph of an incorrectly adjusted gauge is shown in *figure 1*. Correct alignment can be checked by measuring a slip gauge or a feeler gauge using several positions around the very edge of the foot of the micrometer (*figure 2*). If the micrometer is correctly set up, the readings will be the same from all sides of the foot.

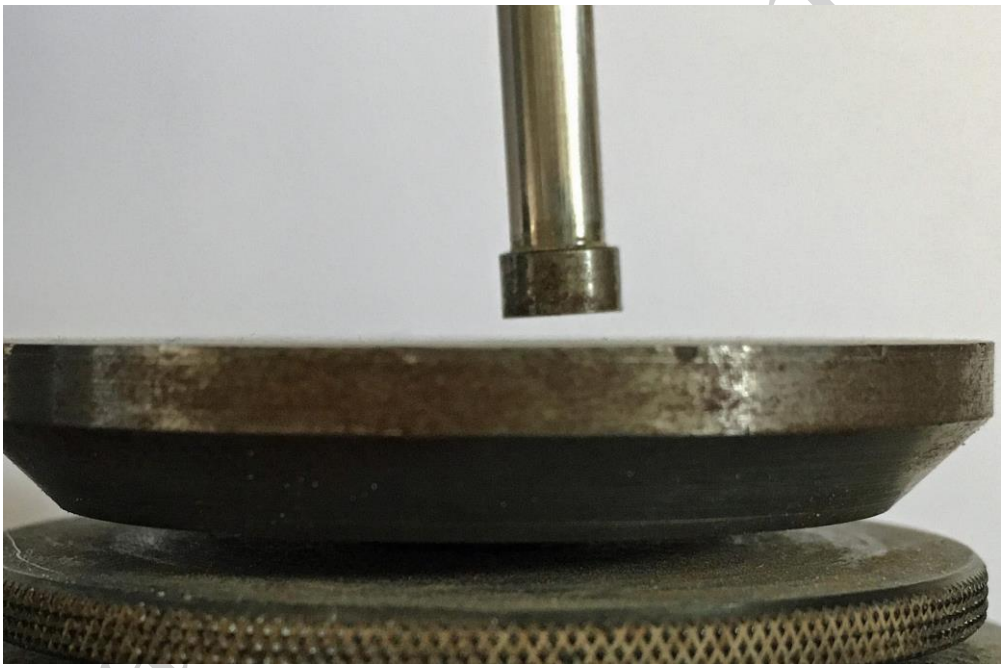

Figure 1. The foot of this micrometer is incorrect and will give the wrong reading.

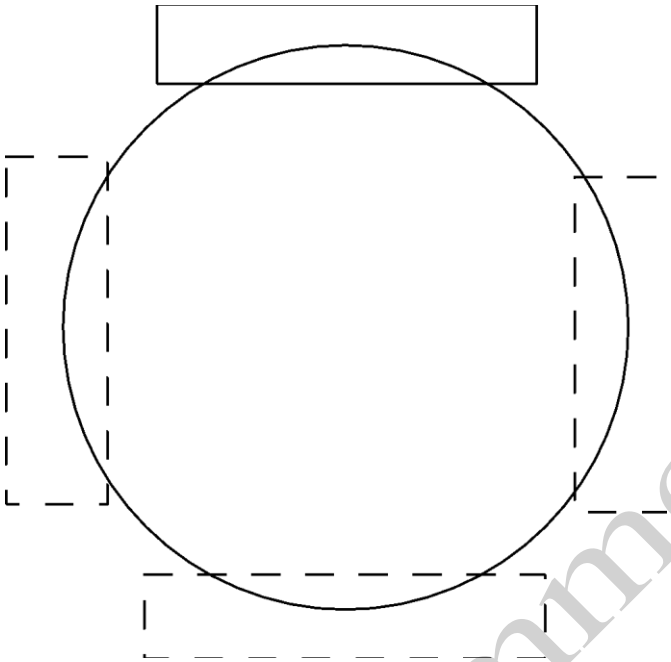

Figure 2. Showing the measurement positions to confirm that the foot is parallel to the platen.

Note that, according to clause 5.5.12 of *ISO 17025:2005* (*5*), test equipment shall "*be safeguarded from adjustments which would invalidate the test result*". It is therefore recommended that parts of the gauge that should not be adjusted during routine use, such as the gauge mount, are made temper-evident. A small sticky label signed by an authorized person and placed over the part is a simple way to achieve this.

5. Determination of bursting volume and pressure (*ISO 4074:2015*, Annex H)

The burst properties of condoms are important properties and are frequently one of the parameters that show up differences in inter-laboratory testing. There can be many reasons for testing variability of which the following are thought to be the most important.

- loading of the condom onto the mandrel;
- correct inflation length;
- slippage of the condom during inflation;
- correct calibration of pressure and volume measuring equipment;

- any corrections for variations in atmospheric pressure owing to the altitude of the test laboratory;
- cleanliness of the air supply hole in the mandrel;
- maintenance of the supply air pressure and the air flow rate; and
- maintenance of the air temperature from the compressor.

Note that recommendations for calibrating the air inflation equipment are given in Annex O of *ISO 4074:2015*.

5.1 Loading of the condom onto the mandrel

Condoms are almost always tested lubricated and a lubricated condom can be difficult to handle. One of the problems resulting from this is that the condom may be stretched too far on loading. In this situation, especially with burst test machines that use a wide supporting mandrel, the lubricant can cause the condom to stick to the mandrel or inflation cuff, preventing the extended condom from recovering fully. As a result, the tested length of the condom is less than it should be. This will lead to a falsely low burst volume and a higher burst pressure.

Note: The opposite situation can occur, especially if the operator is trying too hard to avoid stretching the condom. This can give a condom that is positioned too loosely on the mandrel. In this case, the tested length will be greater than specified giving burst volumes that are erroneously high and burst pressures too low.

The correct way to load the condoms is as follows:

- Remove the condom from the pack, taking care not to damage it (it is recommended that gloves or finger cots are worn).
- Whilst it is permitted to unroll the condom before loading, it will generally be much easier to unroll the condoms directly onto the supporting rod or mandrel.
- Place the rolled condom onto the top of the supporting rod or mandrel and, using the finger tips, stroke the condom down a little at a time, allowing the condom to relax for a few seconds after each stroke.

- Ensure that the condom is not stretched as it is unrolled over the supporting rod/mandrel.

5.2 Ensuring the correct inflation length

As described in 5.1 above, ensuring the correct length of the condom to be inflated is important. Assuming that the condom is loaded correctly, this length will be dictated by the length of the supporting rod or mandrel. This will generally be adjustable and can be checked using the following method or one recommended by the equipment manufacturer:

- Load the condom onto the test machine.
- Clamp the condom.
- Mark the condom, using a suitable pen or marker, as closely as possible to the top of the external clamping collar. Depending on the type of burst test machine, clamping the condom will also start the inflation. In this case, the inflation needs to be stopped as soon as possible so the condom can be marked, or the condom marked as soon as possible and the test aborted so that the condom is not inflated and burst. Some burst testing machines release the condom as soon as inflation is stopped. If this function cannot be temporarily disabled for calibration purposes, it may be necessary to mark the correct inflation length on the condom first.
- Measure the length of the condom to the mark using the condom length measuring mandrel described in Annex D of *ISO 4074:2015* (*6*). The length to the mark should be 150 ± 3 mm.
- If the tested length is outside of these limits, adjust the machine and repeat the measurement to confirm that the tested length is correct.
- Repeat for each inflation head on the test equipment.

5.3 Checking that the condom does not slip during inflation

Most air inflation equipment clamps the condom by inflating an elastic cuff against a rigid collar, clamping the condom in between.

Obviously, no matter how carefully the condom has been loaded onto the test equipment, if it is not firmly held by this clamping mechanism and the condom slips during the test, then errors will be introduced into the results. The effectiveness of the clamping system can be checked in a similar fashion to the inflation length described in 5.2 above. In this case, after marking the condom, allow it to inflate whilst watching the mark. Any slippage in the clamping mechanism will be shown by the mark moving upwards (usually erratically) as the condom inflates. It is also important to check if the machine has inflation cuffs that these do not leak air into the condom, as any unmonitored air entering the condom will give false results. This can be checked by inflating the cuff, turning off the air supply (if the machinery will allow this) and checking that the cuff remains inflated over a period of several minutes. If the testing machine does not permit the cuff to remain inflated when the air supply is turned off, a systematic difference between the volume readings for different test heads may indicate that a cuff is leaking.

Again, check all the inflation heads on the test equipment.

5.4 Calibrating the volume and pressure measuring equipment

Owing to the different types of condom burst equipment used in the industry, no recommendations on the calibration and verification procedures can be made here, other than to calibrate the machines following the manufacturer's instructions. The calibration interval again can be specified by the manufacturer, and will typically be between one and four times a year, although, if the equipment is subject to heavy use, it may be worth calibrating more frequently. If there are any reasons to suspect that the results from a particular machine or test head are not accurate, then investigation and re-calibration should be undertaken immediately.

5.5 Correcting for variations in atmospheric pressure owing to the altitude of the test laboratory

The calibration procedure for inflation test machines will often require the average atmospheric pressure to be entered. It is important that this is adjusted accordingly, especially for test laboratories situated at high altitudes. More detailed instructions will usually be found in the manufacturer's support literature or can be sought directly from the manufacturer.

5.6 Other factors to consider in the burst testing of condoms

- Ensure that the flow rate is within the specified range of 24-30 dm^3/min.
- When a condom is inflated, there is a region of high stress between the part of the condom that is firmly clamped and the adjacent freely expanding part. Owing to the characteristics of latex dipping, this zone is also usually the thinnest. Care must be taken to remove any potential for damage in this area. *ISO 4074:2015* (*6*) specifies that the edge of the rigid collar is rounded with no sharp edges but this edge should be checked regularly to ensure that it has not been nicked or damaged and is still adequately smooth.
- Inflation testing machines can test a lot of condoms between service intervals and in general these condoms will be lubricated. It is not uncommon for lubricant to build up in the various holes supplying air to the condom or the piping connecting the condom to the pressure transducer. Not only can this lubricant build-up affect the accuracy of the test procedures, but contamination of the pressure transducer by lubricant can mean an expensive replacement. Powder and fragments of rubber can also partially or completely block these apertures. It is recommended that there is a daily inspection and cleaning of these apertures, and that the piping to the transducer is inspected and cleaned regularly.
- Be aware of the possibility that the test heads in a multi-headed inflation test machine can differ. Monitor the individual heads and, if any of them appear to be giving consistently different results to the others investigate, and rectify if necessary.
- Consider storing a batch of control condoms and testing a few of them every day, depending on the number of test heads on the machine, before starting to use the inflation equipment. If the results from these control condoms are within the expected trend, that gives an assurance that the equipment is working properly. It can also be

useful in detecting and quantifying any differences between operators. Graphing the results on, say, a mean and range chart will help identify if any significant changes occur.

5.7 Cleanliness of the air supply hole in the mandrel

It should be ensured that the air supply point in the mandrel be cleaned regularly to avoid partial blockage by accumulated powder and lubricant.

5.8 Maintenance of the supply air pressure and the air flow rate

It is recommended that a dedicated air compressor is provided for the inflation tester. Using a compressor which may not have adequate capacity to meet with the demand of maximum use by other operations in the laboratory could cause the air pressure in the inflation tester to have momentary fluctuation and variations from the time of daily calibration checks

5.9 Maintenance of the air temperature from the compressor

It is recommended that the air compressor for inflation tester is located in such a manner that it is not subject to extreme variations during the operation during the day, which could affect the density of the air.

6. Determination of stability and shelf-life (*ISO 4074:2015*, Annexes K and L)

It is a requirement of *ISO 4074:2015* (*6*) that the condoms should comply with the key physical property requirements (that is, burst volume and pressure, freedom from holes and package integrity) throughout their claimed shelf-life. The shelf-life can only be established by a real-time study carried out at 30° C (+5, -2° C). However, a provisional shelf-life can be claimed whilst the real-time study is in progress, provided that satisfactory data from accelerated aging studies are available to support the

claim. A full description of the requirements for real-time and accelerated aging stability studies is given in Annexes K and L of *ISO 4074:2015* (*6*).

The following are points to note when conducting these aging studies:

- The condoms used in the studies must comply with the requirements of *ISO 4074:2015* (*6*). The studies can only be done with condoms that have been stored in bulk for the maximum period of time specified by the manufacturer between dipping and packaging in individual sealed containers. *ISO 4074:2015* (*6*) specifies that this period shall not exceed two years. WHO/UNFPA technical specifications, however, specify a maximum storage period of six months. By agreement with UNFPA, it is acceptable for manufacturers to conduct stability studies on condoms that have been stored for six months between dipping and packaging to verify shelf-life claims for procurement under the WHO/UNFPA prequalification scheme.
  Some manufacturer's formulation may require a certain time period of maturation of condoms before their burst properties could stabilize. It is recommended to allow the required maturation time before the condoms are foiled and this minimum maturation time be validated and applied while conducting stability studies.
- Minimum stability requirements (clause 11.2) (*6*) must be established.
- Three different lots of condoms must be used in the studies. These production lots from where samples are drawn for stability studies should represent the actual normal commercial batch sizes of the manufacturer and not just three sub-lots of the manufacturer
- Select and condition sufficient extra condoms to cover some repeat testing if necessary.
- Ensure that there are contingency arrangements in place in case of equipment breakdown or power failures. You do not want to have to start the studies again from scratch.
- Ensure that the calibration and measurement of temperature are monitored correctly and the trends are reviewed to pick up early warning signals for initiating appropriate corrective and preventive actions.
- Ensure that the system of recording temperature and raising alerts in case of outages in temperature conditions are in a good state of repair throughout the long period of stability studies and the alert signals are responded to immediately.
- The claimed shelf-life cannot exceed five years from the date of manufacture.
- The date of manufacture can be either the date of dipping or the date the condoms were sealed in their individual containers. Note that the labelled date of manufacture cannot be more than two years from the date of dipping or six months to comply with UNFPA requirements, as noted

above.

- Monitor the physical properties of the condoms at intervals during the real-time study. Two methods are described in clause K.2.4 (*6*) of the standard. These are:
  - ❖ Measure the airburst properties of a sample of 125 condoms from each lot and compare against the requirements of the standard, using the AQL of 1.5 (accept on 5 failures or fewer, reject on 6 or more). If one of the three lots of condoms fails, carry out necessary investigation and analyse the root cause of failure. Investigation could also be carried out by analysing more samples from that batch representing that time point. If root cause is common to the other two batches as well, the stability studies should be stopped. If there are no assignable causes for variation at any one specific time point, the study can continue but must be stopped if more than one set of samples fail. At the end of the proposed or claimed shelf-life, carry out the test with larger sample sizes as per the requirements of *ISO 4074:2015* (*6*).
  - ❖ Alternatively, measure the airburst properties of a set of 32 condoms from each lot. Calculate the standard deviation (or 95% confidence interval) for burst volume and pressure. If the mean value, minus three times the standard deviation, approaches the minimum limits defined in the standard (as described in the note to clause K.2.4 {*6*}), this can indicate that the condoms will not pass the requirements of the standard if the study is continued and the stability study should be terminated.
- If the manufacturer has condoms where the shelf-life has been confirmed by a real-time study, then these condoms can be used as controls in an accelerated aging study of a new or modified condom, as described in clause L.3 (*6*).
- If there are no condoms to act as controls in this way, then the provisional shelf-life must be estimated following the procedures in clause L.2 (*6*).
- Existing condoms whose shelf lives were established following the procedures of earlier versions of *ISO 4074* (i.e. 2002 (*7*) and 2014 {*8*}) can be considered to be compliant. However, considering the several changes that have taken place between 2002 and now, the manufacturer should initiate fresh real time stability studies as per the requirements of *ISO 4074:2015* (*6*), for the products that are currently being manufactured.
- If any significant changes are made to the condom formulation, manufacturing procedures or packaging, then the shelf-life will need to be re-confirmed. A significant change, as explained in *ISO 16038, Rubber condoms – Guidance on the use of ISO 4074 in the quality management of natural rubber latex condoms* (*9*), is one that can be regarded as having the potential to

affect performance adversely. If a change is deemed by the manufacturer not to require confirmation of shelf-life, the reasons for this decision and all supporting test data shall be documented.

7. Freedom from holes

7.1 *ISO 4074:2015*, Annex M

The *ISO 4074:2015* (*6*) standard has two methods for performing the test for holes. The volume of water dispensed is dependent upon the average length and average width (taken at 75 ± 5 mm from the closed end excluding the reservoir tip) of 13 condoms as described in the standard.

A. The Water Leak Test (Hang and Roll)

A suspended condom is filled with a specified volume of water and examined for visible water leakage through its walls. In the absence of any leakage, the condom is then rolled on coloured absorbent paper which is subsequently examined for signs of leakage of water from the condom. The test must be carried out exactly as described in the Standard.

Points to note:

- Before testing, using calibrated apparatus, ensure that the volume and temperature of the water dispensed are within the specified limits for the test.
- Ensure that the condom is secured on the mount in such a way as to avoid slippage during water dispensation, especially for the condoms that need volumes of more than 300 dm^3.
- The condom may be tapped gently to remove air bubbles present on the inner surface of the condom.
- It is essential that the rolling is carried out correctly. The water-filled condom must be rolled for a distance sufficient to allow the whole surface of the

condom to contact the paper. This distance is frequently underestimated. When training operators, it can be helpful to mark the condom to show how far the condom must be rolled. The condom must be rolled through at least two complete revolutions (WHO/UNFPA do not recommend rolling more than 10 revolutions).

- Ensure that the correct amount of pressure is applied to the condom. The hand (with fingers spread) should be maintained 25 to 35 mm above the paper.
- When testing the closed end of the condom, maintain a similar level of pressure as when rolling and do not slide the condom over the paper.
- The coloured absorbent paper should be one that makes it easy to identify the blots made by the presence of holes on the condom wall. It should also allow for the rolling of the condom body for the required revolutions as per ISO 4074. Under no circumstances shall multiple absorbent papers be joined using adhesive tape.
- The condom walls may be carefully wiped with soft absorbent cloth or paper to remove excess moisture and lubricant thus allowing for easier detection of leaks.

B. The Electrical Test

Points to note:

- The equipment shall be routinely calibrated and/or verified for effectiveness, and maintained as per manufacturer's specifications. This includes routine changing of the electrolyte solution as build-up of lubricant may affect the efficacy of the test. In addition to calibration, the equipment and the technique should be verified on routine basis for effectiveness in detecting the holes
- The different parameters that affect the test, such as voltage, should be checked before each batch/lot test, using calibrated apparatus, for conformity to specified limits.

- Not more than 25 mm of the condom should be left unexposed to the

electrolyte.

- Any leaks detected by the system should always be confirmed by the rolling method described in the Water Leak Test. Note that *ISO 4074:2015* (*6*) specifies the Hang and Roll method must be used - not the *ASTM D3492* Hang and Squeeze method (*10*).
- Note that the condoms have to be observed during filling in order to detect any holes (see M 3.3.7, third line {*6*})

7.2 ASTM D3492 – 15, Annex A3

A. The Water Leak Test (Hang and Squeeze)

This method is very similar to the Hang and Roll method except that the condom is not rolled. Instead, pressure is applied to the condom by gently squeezing it whilst it is hanging, full of water, on the test equipment. The test must be carried out exactly as described in the *ASTM D3492* (*10*) Standard.

Points to note when using this method are:

- After filling with water, the body of the condom should be tapped gently to dispel any air bubbles present on the inner surface of the condom.
- Do not apply too much pressure by squeezing too hard. The correct amount of distension of the filled condom is shown in *figures A3.3* to *A3.5* in the ASTM Standard (*10*).
- When checking the body of the condom, gently rotate the condom so that the entire surface is inspected.
- When examining the condoms for signs of leakage, ensure that any water droplets on the outside of the condom are the result of leakage and not water splashed onto the condom from any external source. If necessary, gently dry the outside of the condom with a paper towel and re-check.

8. Visibly open seals (*ISO 4074:2015*, Annex N)

This test is performed using samples which are drawn for conducting the tests for Freedom from Holes and Visible Defects.

The individual sealed containers are examined by visual observation for any visibly open seals. Defects may include improperly formed seals, condoms getting trapped in sealing area, uneven or very narrow sealing edges leading to open seals and leakages. However, it should be noted that these packaging "defects" are not specified in *ISO 4074:2015* (*6*).

It is recommended that the test laboratory has the display of defects related to visibly open seals to serve as examples of workmanship criteria so that consistency is maintained in conducting the test. The defectives observed should be preserved for reference.

9. Visible defects (*ISO 4074:2015*, Annex M and *WHO/UNFPA Technical specifications for male latex condoms*)

The test for visible defects is conducted on the same set of samples taken for the test for Freedom from Holes.

After performing the test for visibly open seals, the individual sealed containers are opened by pushing the condoms to one side of the pack and opening the seals, taking care that the condom is not damaged by the rough edges of the seals, nor sharp instruments such as scissors or finger nails. The condoms are unrolled and examined by visual observation under bright light. It should be ensured that all the parts of the condoms are completely covered by the visual observation. The visual defects are classified as Critical and Noncritical defects with corresponding AQLs of O.4 and 2.5. The section on Workmanship and Visible Defects on the WHO/UNFPA Specification (*6*) details the list of Critical and Noncritical defects. This section also lists the minor imperfections, which do not affect the properties of the condoms, but are considered as potential points for elimination with appropriate quality improvement projects. Personnel should be trained for the ability to detect the visible defects and to

correctly classify them. Having an approved workmanship criteria album will be useful to avoid any disputes. It is recommended to have a display of specific visual defects in the laboratory for the operators to easily identify and classify the defects.

10. Determination of package seal integrity (*ISO 4074:2015*, Annex N)

Unless specified otherwise in the procurement contract and purchase order, the Package Integrity test[1] specified in Annex N of *ISO 4074:2015* (*6*) shall be used to test package integrity. For condoms intended for distribution to high altitude regions or to be distributed by air freight, the alternative "dry vacuum method" described in Annex 2 of the revised *World Health Organization/United Nations Population Fund Technical specifications for male latex condoms* (*3*) may be specified.

When conducting the test according to the method specified in Annex N of *ISO 4074:215* (*6*), the following points should be noted:

- Working with a vacuum is potentially dangerous. Eye protection should be used when carrying out this test.
- The vacuum chamber should be closable with an air tight transparent lid so that the defective packs can be easily observed during the test.
- A vacuum level of 20 ± 5 kPa absolute must be used. That is approximately 20% of normal atmospheric pressure at sea level. Unfortunately, some gauges will read from 0 to 100 kPa whilst others may read from 100 (or -100) to 0 kPa (see *figure 3*). This can be confusing. If the gauge reads from 0 to 100, the correct level of vacuum will be the figure of 20 kPa: if the gauge

[1] The seal on the individual condom container, whether of the standard foil pack or the "butter dish" container can, at times, be compromised. This can be caused by several factors, including misaligned sealing jaws, excessive lubricant, a misaligned or poorly rolled condom being trapped in the seal, etc. In addition, the foil may contain pinholes or, if the information on the foil is stamped on, rather than ink-jet printed, the stamping may damage the foil. All in all, there are many ways in which the individual condom container can contain small holes. A consequence of this is that lubricant can leak out and, if not detected, can contaminate all the other condom containers within the same pack. In addition, a compromised foil can expose the condom to oxygen which could cause premature degradation. For this reason, it is necessary to test the integrity of the packages.

reads the other way, the correct vacuum level will be 80 (or -80) kPa (*figure 3*). In case of doubt, remember that it is the greater level of vacuum that must be used. It will typically take at least 20 seconds - often considerably longer - for a vacuum pump to evacuate the chamber to this level. Changes in the time taken to reach the desired vacuum level can be indicative of complications in the test system or an inaccurate level of vacuum being used.

- The water level should be such that the condom packages are at least 25 mm below the surface.
- The number of packages in the chamber should be restricted so that all the packages can be clearly observed.
- A dye is often used to help detect leakage into the containers and the amount used should not obscure observation of the packages.
- If a dye is used, it should be easily washable and should not leave any deposit of colour building up as that would obstruct the observation of leakages. The vacuum container and the lid should be maintained clean.
- Observe the condom packages as soon as the vacuum pump starts - do not wait until the specified vacuum level has been reached to start the observation. By that time, all the air in a defective package may have been expelled and the stream of bubbles will have ceased.
- All of the individual containers must be opened to check for the presence of water inside. This is where the dye can be helpful, to distinguish between lubricant and any water that may have entered the pack.

Figure 3. A pressure gauge reading from -100 to 0 kPa. In this case, the correct vacuum level for the test would be -80 kPa (red numerals).

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