

## Guidance on Conducting Post Market Surveillance Testing of Condoms

### Background

Good quality condoms conforming to the WHO/UNFPA Technical Specification for Male Latex Condoms 2017 have excellent storage properties. The combination of individual condom packaging, inner boxes and shipping containers is designed to protect the condoms during shipping and storage. Nevertheless, storage under poor conditions and/or rough handling during shipping might adversely affect the properties of the condoms. Exposure to such adverse conditions is potentially more likely once the condoms have left control of the purchaser and are in the wider distribution chain. For this reason periodic surveillance testing of product recovered from the field is recommended to confirm that the condoms are still fit for purpose.

Surveillance testing may have to be undertaken when there are complaints about condoms, particularly if the complaints are clustered and associated with one specific product or even a single lot of product. In such cases sample sizes can be severely limited and it may be necessary to limit testing to just one property. The selection of sample sizes for such testing can be challenging and the results may be of limited use if only a small number of samples are available.

### Sampling

In order to conduct post market surveillance testing on male latex condoms it might be necessary to recover condoms from any of the following locations:

- Warehouses
- Distribution centres
- Wholesalers
- Clinics
- Retail Outlets

A key issue when recovering samples for surveillance testing is often the sample size and lot integrity. If single lots are being tested, for example one lot from a number of manufacturers, then ideally the sampling plans given in Annex B of *ISO 4074* should be used. If possible samples should be taken from at least three lots from each manufacturer to give some idea about lot to lot homogeneity. If multiple lots from a single manufacturer are being evaluated then the sampling plans of Annex A of *ISO 4074* are acceptable. If sample sizes are limited then it may be necessary to test only for selected properties.

Sample only for the tests that are needed to check on the parameters in question. Obtaining sufficient samples from warehouses, distribution centres and wholesalers is not usually problematic but sampling from clinics and retail outlets often means that sample sizes have to be restricted. This may limit the types and numbers of tests that can be completed.

If sample sizes are restricted then sample sizes should still be selected from *ISO 2859-1, Sampling procedures for inspection by attributes, Part1. Specification for sampling plans indexed by acceptance quality level (AQL) for lot-by-lot inspection*. Try and select sampling plans that have at least a 95% probability of acceptance if the quality of submitted lots is at the limit of the specified AQL (refer to tables X-A through to X-R of *ISO 2859-1* for the operating characteristic curves and acceptance probabilities of the sampling plans). Do not use sample sizes that are consistent with *ISO 2859-1*. Do not use sample sizes that fall between the specified sample sizes in the tables (for

example Table II-A).). Doing so can result in situations where it is not possible to make a decision about whether the product sampled conforms to the specification. If there are insufficient samples available to use a specified sample size then go down to the next lowest specified sample size for which there are enough samples.

For performance requirements, such as burst properties, freedom from holes and package, try and avoid zero accept sampling plans whenever possible (for example a sample size of 50 for an AQL of 0.25 with an acceptance number of 0). These sampling plans generally have poor operating characteristic curves which can lead to type I and type II errors (i.e. incorrect rejection of a true null hypothesis and failure to reject a false null hypothesis respectively, or more simply, false positive and negative results). If forced due to shortage of samples to use zero accept sampling plans then be cautious about any conclusions that are reached.

At the time of sampling full details about the lots being sampled including the lot numbers, expiry dates and storage conditions should be noted. More information about taking samples is given in Section 3, Guidelines for Procurement. Whenever possible a sampling agency should be used and samples should be taken from lots using procedures to ensure the random selection of condoms from within the lot.

In some cases it may be necessary to combine samples from more than one lot in order to achieve an adequate sample size for testing. This should be regarded as a situation of last resort and is best avoided. Full details of the lots sampled must be recorded and note made of the expiry date for each lot sampled. If possible samples from the different lots that are to be combined should be kept separate throughout the testing process to permit

If the test laboratory is located some distance from the location at which the condoms are being sampled then consideration has to be given to the transport arrangements needed to get the condoms to the laboratory. It is essential to ensure that the condoms will not be subjected to any adverse conditions in transit that could affect the results of the tests. Sending samples by airfreight might, for example, compromise the outcome of any testing for package integrity. The use of data loggers to monitor temperatures during shipment can be considered, particularly if the condoms are being shipped from or through countries with hot climates.

## **1. Testing**

The primary focus for testing natural rubber latex male condoms should be the critical performance parameters, i.e. burst properties, freedom from holes and package integrity. Other properties, such as dimensions, are unlikely to change during storage or shipping. Burst properties can be evaluated on a variables basis as well as on an attribute basis (i.e. conformance to the 1.5 AQL for burst properties). Information about average burst volume and pressure, their associated standard deviations and the frequency distributions of the results can be extremely useful in trying to determine if any significant changes have occurred. Comparisons can be made with the original manufacturer's data and the pre-shipment test results. The statistical significance of any changes in properties can be readily assessed by the t-test or analysis of variance (ANOVA). Using such methods may be particularly informative in situations where there are insufficient samples available to make reliable estimates of conformity to the AQLs on an attribute basis.

## **2. Selection of Laboratories**

Laboratories used for surveillance testing must be accredited to ISO 17025 for the tests being carried out. The laboratories should also participate in an appropriate international inter-laboratory proficiency scheme. Ideally the same laboratory that did the original pre shipment testing should be

used. This makes the comparison of results much easier and more reliable, and permits samples that have been retained under controlled conditions by the test laboratory to be retested if necessary.

For more information about the selection of laboratories refer to the [document “Condom Quality Assurance”](#)

Consideration should also be given when selecting test laboratories to any local customs and import restrictions. Some countries have restrictions on the import of condoms without testing and these rules can even be applied to samples being imported solely for test purposes. Check with the laboratories concerned to make certain that all rules relating to the import of products for testing are followed.

### **3. Interpretation of Results**

Although lot conformity is assessed on an attribute basis, the use of means and standard deviations whenever possible is recommended. This primarily applies to burst testing. Trends in burst properties, particularly when compared to the results from pre-shipment testing, can provide early warning of potential problems.

Reviewing the burst result histograms can reveal very interesting information. Bimodal (or even poly-modal) distributions of burst pressure and/or volume are indicators of poor lots homogeneity. In some cases this might indicate that the product is counterfeit, the lot in question consisting of mixed condoms from different lots or even condoms from different manufacturers. If counterfeit product is suspected then forward all of the details to the manufacturer whose name is marked on the pack. The manufacturer should be able to determine the authenticity of the product from the lot number. Counterfeiters commonly make small mistakes with labelling so return samples of the packaging and any information received with the product to the manufacturer for checking.

If regular post market surveillance testing is being carried out on products from a specific manufacturer then analysis of trends over time can provide extremely useful information. Plotting charts, as described in document [“Condom Quality Assurance – Annex 2”](#), for example, is a very powerful method of identifying any concerning trends in product quality. Early identification of an unacceptable trend might, for example, permit a manufacturer to carry out corrective and preventative actions before the product goes out of specification and lots are rejected. Charts can also be used to identify situations where manufacturers may have made changes to the product or production processes and failed to inform the purchaser. Comparing trends for pre-shipment test results with those from surveillance testing might also identify problems relating to the shipping and storage of a product.