

Corrigendum



Male Latex Condom: Specification, Prequalification and Guidelines for Procurement, 2010

Revised - April 2013

The following list provides a description of changes made to the Male Latex Condom: Specification, Prequalification and Guidelines for Procurement, 2010 since the original version was printed.

Some versions may have been partly updated with the information in this corrigendum.

For the complete revised PDF version of the guidelines, please visit:

<http://www.unfpa.org/public/procurement>

Page 27 2.1 General requirements, add the following statement after the fourth paragraph immediately before the table:

UNFPA requires confirmation that condoms comply with the minimum stability requirements specified in ISO 4074 during prequalification by testing condoms that have been oven conditioned for (168 ± 5) hours at (70 ± 2) °C.

Page 29: 2.2 Performance requirements, Table headed Performance requirements, Bursting Volume and pressure:

Amend third row starting “Requirement” to read:

Requirement	<p>Minimum bursting requirements as listed below:</p> <p>AQL 1.5</p> <p>Volume:</p> <p>16.0 dm³ for condoms with widths less than 50.0 mm</p> <p>18.0 dm³ for condoms with widths from 50.0 mm up to 55.5 mm</p> <p>22.0 dm³ for condoms with widths greater than or equal to 56.0 mm</p> <p>Pressure: 1.0 kPa (for all widths)</p> <p>The width is defined as the mean lay-flat width of 13 condoms measured in accordance with the relevant annex of <i>ISO 4074</i> at a point (75 ± 5) mm from the closed end rounded to the nearest 0.5 mm</p>
--------------------	---

Page 30: 2.2 Performance requirements, Table of performance requirements, Bursting volume and pressure after oven conditioning (optional: see Annex 1)⁶:

Amend second row in table starting “Testing” to read:

Testing	Condition the samples in accordance with the relevant annex of <i>ISO 4074</i> for (168 ± 2) hours at 70 °C. Remove from oven and keep the packages at (25 ± 5) °C until tested. Within 96 hours but no sooner than 12 hours after removal from the oven, determine the bursting volume and pressure in accordance with the test method in the relevant annex of <i>ISO 4074</i> and the relevant clause in <i>ISO 4074</i> .
----------------	--

Page 30: 2.2 of Performance requirements. Table of performance requirements, Freedom from holes and visible defects:

Amend rows starting “Sampling” and “Testing” to read:

Sampling	<i>ISO 2859-1</i> General Inspection Level I, but at least Code Letter M. For prequalification testing at least Code Letter N as specified in Annex B of ISO4074 shall be used.
Testing	In accordance with the relevant annex of ISO 4074.

Page 30: 2.2 of performance requirements, table of performance requirements, Pack seal Integrity

Amend rows starting “Sampling” and “Requirement” to read:

Sampling	<i>ISO 2859-1</i> Inspection Level S-3 .
Testing	In accordance with the package integrity test method in the relevant annex of <i>ISO 4074</i> .
Requirement	AQL 2.5

Page 33: 2.3 Design Requirements, Table of design requirements, Individual package materials and markings:

Amend first and third rows starting “Sampling” and “Requirement” to read:

Sampling	In accordance with <i>ISO 2859</i> Inspection Level S-3 .
Requirement	The colour, print design and identification markings, including Pantone references and font sizes, shall be as specified by the buyer and annexed to this specification. The individual package shall have the following markings: <ul style="list-style-type: none"> • manufacturer’s name; • LOT number or LOT identification code (printed at the time of packaging, not pre-printed); • expiry date: month and year labelled expiry date; • date in a language to be specified by the purchaser. <i>Manufacturing date: Month-and-year manufacturing date can be added if required by purchaser.</i> AQL 2.5

Pg. 34 Clause 2.4 Packaging for Shipment:

Delete “”prequalification” from the first clause to read:

“Inspections or verifications in this section will generally be carried out during LOT-by-LOT Pre-shipment compliance testing and periodic inspections.”

Add the following text before Table 2:

The following tables summarize the different requirements for prequalification and pre-shipment testing. For pre-shipment testing, which is required prior to the consignment of condoms, samples sizes will be selected in accordance with ISO 4074: 2002 Annex A and will be inspected and tested against technical specifications that govern the respective agreement or purchase orders. All testing activities will be conducted under ISO 17025 accreditation.

For prequalification testing, UNFPA requires that three lots of condoms be randomly selected for testing. At the time of the prequalification inspection, the inspected factory may not be producing condoms against the WHO/ UNFPA Male Latex Condom Specification, 2010. Thus, the manufacturer may not be producing condoms that comply with the full requirements of the **WHO/UNFP Male Latex Condom Specification, 2010**. This applies in particular to requirements for package marking and labelling, but may apply to other properties such as dimensions. Inspectors and/or inspection companies shall select condom lots for testing that comply as closely as possible with the requirements of the WHO/UNFP Male Latex Condom Specification 2010. The selected sample must comply with and will be tested against the requirements of ISO 4074: 2002.

UNFPA includes testing condoms that have been oven conditioning for (168 ± 5) hours at (70 ± 2) °C for bursting pressure and volume during prequalification testing to confirm that the condoms comply with the minimum stability requirements specified in Clause 7.2 of ISO 4074:2002. In anticipation of changes in the next edition of ISO 4074 (which is expected to be published later in 2013) UNFPA also requires testing for freedom from holes and visible defects, and package integrity after oven conditioning for (168 ± 5) hours at (70 ± 2) °C for prequalification testing.

Page 37 Table 2. Summary of prequalification tests and requirements:

Amend row starting “Freedom from holes” to read:

Freedom from holes (before and after oven conditioning for (168 ± 5) h at (70 ± 2) °C	Level G-1 Minimum Code Letter N	AQL 0.25
---	---	----------

Amend row starting “Visible defects” to read:

Visible defects(before and after oven conditioning for (168 ± 5) h at (70 ± 2) °C	Level G-1 Minimum Code Letter N	Critical defects: AQL 0.4 Non-critical defects: AQL 2.5
---	---	--

Amend row starting “Package integrity” to read:

Package integrity(before and after oven conditioning for (168 ± 5) h at (70 ± 2) °C	Level S-3 Minimum Code Letter H	AQL 2.5
---	---	---------

Page 38: Table3. Summary of LOT-by-LOT Pre-shipment compliance testing and requirements

Remove “Minimum Code Letter M” from the first and second rows starting “Bursting volume (before and after oven conditioning)” and “Bursting pressure (before and after oven conditioning)” to read:

Bursting volume (before and after oven conditioning)	Level G-I	Minimum volumes: 1. 16.0 dm ³ for condoms with widths less than 50 mm 2. 18.0 dm ³ for condoms with widths from 50 mm to 55.5 mm 3. 22 dm ³ for condoms with widths greater than 56 mm AQL 1.5
Bursting pressure (before and after oven conditioning)	Level G-I	Minimum pressure: 1.0 kPa AQL 1.5

Page 38: Table3. Summary of LOT-by-LOT Pre-shipment compliance testing and requirements

Amend sixth row starting “Package integrity” to read:

Package integrity	Level S-3	AQL 2.5
-------------------	------------------	---------

Page 38: Table3. Summary of LOT-by-LOT Pre-shipment compliance testing and requirements

Add an additional row to Table 3 to read:

Individual package materials and markings	Level S-3	Compliant with procurement specifications AQL 2.5
---	-----------	--

Page 65

Replace the following text:

“Manufacturer/applicant may also provide a CD-ROM of this material. The CD-ROM must be in addition to, and not in place of, the hard copy of the documentation”.

With:

“Manufacturer must provide an electronic version (CD or USB) of this material. The electronic version must be in addition to, and not in place of, the hard copy of the documentation.”

Page 72 Clause 3.8 Risk management plan:

Replace the text:

“A summary of the risk management assessment under-taken in accordance with ISO 14971”.

With:

“A summary of the risk management assessment of **the manufacturing process** undertaken in accordance with *ISO 14971*”.

Pg. 99

Amend the following text:

“The Pre-shipment compliance testing reports are sent to the purchaser, who will approve the consignment for shipment. It is recommended that a certificate of compliance and a summary of the results of compliance testing be sent to the appropriate national regulatory authority to comply with any national regulatory requirements that may exist.”

To read:

“The Pre-shipment compliance testing reports are sent to the purchaser, who will approve the consignment for shipment. It is recommended that a certificate of compliance and a summary of the results of compliance testing be sent to the appropriate **consignee and** national regulatory authority to comply with any national regulatory requirements that may exist. **It is also recommended that a summary of the test results of compliance testing is sent to the manufacturer irrespective of the results to give the manufacturer clear evidence of the outcome of the tests.** ”

Pg. 140 Hotline

Update the email address for the Hotline to: HELPLINEcondomquality@fhi360.org

Questions or comments regarding this corrigendum can be emailed to: QA@unfpa.dk