### ANNEX V
### GLOSSARY OF TERMS AND ABBREVIATIONS

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acceptance number</td>
<td>The highest number of non-compliers (failures) allowed in a specific test from a selected sample.</td>
</tr>
<tr>
<td>AFRO</td>
<td>WHO Regional Office for Africa.</td>
</tr>
<tr>
<td>Aggregate analysis</td>
<td>A retrospective method of assessing whether the total number of defective condoms found in a series of LOTS is within the normal statistical bounds of the specific sampling plans being used. It helps determine accept/reject numbers for the total sample size obtained by aggregating the results from a number of LOTS for any specific AQL and aggregated sample size (N).</td>
</tr>
<tr>
<td>AQL</td>
<td>Acceptable Quality Limit. The quality level that is the worst tolerable process average when a continuing series of LOTS is submitted for acceptance sampling (ISO 2859–1). N.B. Manufacturers should be consistently achieving a process average that is better than the AQL.</td>
</tr>
<tr>
<td>Aseptic technique</td>
<td>Precautionary measures taken to prevent external contamination of materials, samples, and culture media; employed during testing.</td>
</tr>
<tr>
<td>Batch</td>
<td>Sometimes used in place of “LOT” (see definition of LOT). (WHO recommends that “LOT” be used when referring to condoms.) Can also refer to a homogenous quantity of latex that has been compounded and is ready for dipping, from which several LOTS will be made. Or, to describe a quantity of individual raw materials.</td>
</tr>
<tr>
<td>Bead</td>
<td>The thickened ring formed at the open end of the condom.</td>
</tr>
<tr>
<td>Bid security</td>
<td>A guarantee from a bank that the bidder will perform its obligations in regard to the bid.</td>
</tr>
<tr>
<td>Bioburden</td>
<td>The population of micro-organisms on a raw material, component, product, packaging or equipment.</td>
</tr>
<tr>
<td>Bioluminescence</td>
<td>When bacterial adenosine triphosphate (ATP) reacts with firefly luciferin and luciferase, light is emitted. Bioluminescence tests are designed to measure the amount of light produced, which will be related to the number of micro-organisms present in the sample.</td>
</tr>
<tr>
<td>CCP</td>
<td>Comprehensive Condom Programming.</td>
</tr>
<tr>
<td>CDC</td>
<td>U.S. Centers for Disease Control and Prevention.</td>
</tr>
</tbody>
</table>
CE mark
On condom packaging, a mark certifying that the product conforms to the essential requirements of the European medical device directive 93/42/EEC.

cfu
Colony forming units—a unit of measure of the level of microbial contamination of a product.

C/L
Commercial letter of credit.

Compliance testing
A regime of testing to verify that a LOT complies with the specification.

Condom
Medical device that is intended to be worn on the penis during sexual activity for purposes of contraception and to prevent the spread of sexually transmitted infections. Condoms are usually made from natural rubber latex but may also be made from synthetic materials, such as polyurethane.

Condom procurement cycle
The time taken from making the initial forecast to the completion of the final shipment.

Comprehensive Condom Programming
A strategic approach to create the demand for and ensure the supply of good-quality male and female condoms.

Confirmatory testing
Testing carried out on receipt of a product in country.

Consumer pack
A wallet or carton into which one or more foil packages are inserted for marketing purposes.

DFID
U.K. Department for International Development.

Design Requirements
Characteristics of the condom that are specified according to the buyer’s requirements.

DKT
A social marketing company.

DRA
Drug regulatory authority.

EOI
Expression of Interest.

Expiry date
The date at which the product is no longer considered acceptable for use.

Exterior shipping carton
The container into which a number of inner boxes are packed.

FEFO
First expiry, first out.
### General Requirements

The general quality characteristics of condoms that are verified before supply commences and that are not expected to vary from LOT to LOT.

### GMP

Good manufacturing practice is a code of practice aimed at ensuring that product is consistently manufactured to the required standard.

### GTZ

Deutsche Gesellschaft für Technische Zusammenarbeit.

### HIV

Human immunodeficiency virus.

### ICH

International Conference on Harmonization.

### INCOTERMS

Defines when the ownership, responsibility and liability for a shipment is transferred from the supplier to the client and/or receiving country.

### Inner box

A box used to contain a convenient number of condoms in packages or consumer packs. Inner boxes typically contain 100–200 condoms; where a gross (144 condoms) is used as the unit of purchase, inner boxes are usually specified to contain one gross.

### Inspection level

The degree of examination of the LOT, as specified in ISO 2859–1.

The higher the inspection level, the more samples will be tested and, hence, the lower the risk of faulty products reaching the end user.

### IPPF

International Planned Parenthood Federation.

### IPPF/ICON


### IUD

Intrauterine device.

### ISO

International Organization for Standardization.

### ISO/TC 157

International Organization for Standardization, Technical Committee 157 for Non-Systemic Contraceptives and STI Barrier Prophylactics.
<table>
<thead>
<tr>
<th>Term</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Length</td>
<td>The length of the condom measured from the open end to the tip, excluding any reservoir.</td>
</tr>
<tr>
<td>LOT</td>
<td>A quantity of condoms of a single grade, class, size and composition, manufactured under essentially the same conditions. With certain exceptions, all the condoms comprising a LOT will have identical formulation; the same dimension, colour, shape, and surface texture; be manufactured on the same production line; and be vulcanized under the same conditions.</td>
</tr>
<tr>
<td>LOT number or code</td>
<td>A unique identifying alphanumeric code assigned to a LOT.</td>
</tr>
<tr>
<td>Lowry method (modified)</td>
<td>A method for determining the water-extractable protein levels in latex products.</td>
</tr>
<tr>
<td>Manufacture date</td>
<td>The date on which the condoms were dipped.</td>
</tr>
<tr>
<td>MPN</td>
<td>Most Probable Number.</td>
</tr>
<tr>
<td>MSDS</td>
<td>Material Safety Data Sheet.</td>
</tr>
<tr>
<td>MSH</td>
<td>Management Sciences for Health.</td>
</tr>
<tr>
<td>National Regulatory Authority</td>
<td>A regulatory body with authority in a specific country to control the importation and distribution of medical products. See also Regulatory authority.</td>
</tr>
<tr>
<td>Opportunistic pathogen</td>
<td>An organism that does not normally cause disease but becomes pathogenic under certain circumstances.</td>
</tr>
<tr>
<td>Package</td>
<td>The foil sachet in which the condom is sealed after manufacture.</td>
</tr>
<tr>
<td>PATH</td>
<td>Program for Appropriate Technology in Health.</td>
</tr>
<tr>
<td>Performance Requirements</td>
<td>The critical tests of quality that all LOTS must pass in order to provide adequate consumer protection.</td>
</tr>
<tr>
<td>Prequalification</td>
<td>The steps taken by the buyer to verify a manufacturer’s suitability to provide condoms of the required quality. The WHO/UNFPA Prequalification Scheme includes periodic assessment of manufacturing dossiers, testing of samples and factory inspection.</td>
</tr>
<tr>
<td>Pre-shipment compliance testing</td>
<td>A regimen of compliance tests carried out before a shipment leaves the supplier’s factory.</td>
</tr>
<tr>
<td>Term</td>
<td>Definition</td>
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<tr>
<td>-----------------------------</td>
<td>-----------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Process average</td>
<td>The percentage of condoms that is non-conforming over a defined time period or quantity of production. It is calculated for each requirement detailed in the WHO/UNFPA Specification by dividing the number of non-conforming condoms by the total number of condoms tested. Ideally, the process average for a specific attribute should be not greater than half the specified AQL.</td>
</tr>
<tr>
<td>PSI</td>
<td>Population Services International.</td>
</tr>
<tr>
<td>Random sample</td>
<td>A sample of condoms drawn randomly from a LOT for testing purposes.</td>
</tr>
<tr>
<td>Regulatory authority</td>
<td>A national or international body set up to oversee the safety, efficacy and quality of medical devices, including condoms, imported and distributed within a country or region.</td>
</tr>
<tr>
<td>Rejection number</td>
<td>The number of non-compliers (failures) in a test sample that will cause a LOT to be rejected.</td>
</tr>
<tr>
<td>RHSC</td>
<td>Reproductive Health Supplies Coalition.</td>
</tr>
<tr>
<td>Reservoir</td>
<td>A narrow portion of the condom at the closed end, designed to contain ejaculate. The reservoir is sometimes called the teat.</td>
</tr>
<tr>
<td>Reverse osmosis (RO)</td>
<td>A process used to provide pure water by removing unwanted salts and micro-organisms by applying pressure in the opposite direction of natural osmotic flow across a semi-permeable membrane.</td>
</tr>
<tr>
<td>Sampling plan</td>
<td>A specific plan that indicates the number of units (condoms) from each LOT that are to be inspected (sample size) and the associated criteria for determining the acceptability of the LOT (acceptance and rejection numbers).</td>
</tr>
<tr>
<td>SDA</td>
<td>Sabourauds Dextrose Aga.</td>
</tr>
<tr>
<td>SMF</td>
<td>Site Master File summary.</td>
</tr>
<tr>
<td>Shelf-life</td>
<td>The period of time after manufacture that the product is considered acceptable for use.</td>
</tr>
<tr>
<td>Social marketing</td>
<td>The use of commercial marketing techniques to distribute, promote and sell products and services of social importance, often at a subsidized price.</td>
</tr>
<tr>
<td>SOP</td>
<td>Standard operating procedure.</td>
</tr>
<tr>
<td>Term</td>
<td>Definition</td>
</tr>
<tr>
<td>---------------------------</td>
<td>-----------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Specification</td>
<td>A detailed statement of a product’s requirements as established by the buyer. Usually, a specification is based on an established standard.</td>
</tr>
<tr>
<td>Standard</td>
<td>A detailed statement of the minimum acceptance requirements, as established by a national or international regulatory authority.</td>
</tr>
<tr>
<td>STIs</td>
<td>Sexually transmitted infections.</td>
</tr>
<tr>
<td>SWAp</td>
<td>Sector-wide approach.</td>
</tr>
<tr>
<td>TSA</td>
<td>Travel subsistence allowance.</td>
</tr>
<tr>
<td>Total Viable Count (TVC)</td>
<td>The number of living micro-organisms in a given sample.</td>
</tr>
<tr>
<td>UN</td>
<td>United Nations.</td>
</tr>
<tr>
<td>UNAIDS</td>
<td>Joint United Nations Programme on HIV/AIDS.</td>
</tr>
<tr>
<td>USAID</td>
<td>United States Agency for International Development.</td>
</tr>
<tr>
<td>USFDA</td>
<td>United States Food and Drug Administration.</td>
</tr>
<tr>
<td>Ultraviolet irradiation (UV)</td>
<td>Normally emitted at a wavelength of 254 nm; may be used to diminish or eliminate bioburden in process water.</td>
</tr>
<tr>
<td>Viscosity</td>
<td>The resistance to flow of a fluid.</td>
</tr>
<tr>
<td>Wall thickness</td>
<td>The thickness of the latex film.</td>
</tr>
<tr>
<td>Width</td>
<td>The dimension measured 30 mm from the open end, at a right angle to the length of the condom when it is unrolled and laid flat without any creases.</td>
</tr>
<tr>
<td>WHO</td>
<td>World Health Organization.</td>
</tr>
<tr>
<td>WHO/RHR</td>
<td>World Health Organization, Department of Reproductive Health and Research.</td>
</tr>
</tbody>
</table>
Various external documents form part of the WHO/UNFPA Specification, and the buyer may wish to mention them in any Invitation to Bid or order sent to the supplier. In every case the edition of the document is the one in force on the date of the Invitation to Bid.

1 International Standards

These are standards published by the International Organization for Standardization (ISO). Copies can be obtained from the national standardization organization in the buyer’s country or:

**International Organization for Standardization**
ISO Central Secretariat
1, ch. de la Voie-Creuse
CP 56
1211 Geneva 20, Switzerland
Telephone: +41 22 749 0111
E-mail: central@iso.org
Web site: http://www.iso.org

**Latex condoms**
ISO 4074:2002 Natural Latex Rubber Condoms Requirements and Test Methods
Cor 1:2003
Cor 2:2008

**Testing methods**
ISO 4074:2002 Annex A Sampling Plans Intended for Assessing Compliance of a Continuing Series of LOTS of Sufficient Number to Allow the Switching Rules to Be Applied
ISO 4074:2002 Annex D Determination of Length
ISO 4074:2002 Annex E Determination of Width
ISO 4074:2002 Annex F Determination of Thickness
ISO 4074:2002 Annex H Oven Treatment of Condoms
ISO 4074:2002 Annex I Determination of Force and Elongation at Break
ISO 4074:2002 Annex M Tests for Package Integrity
ISO 12243:2003 Medical Gloves Made from Natural Rubber Latex Determination of Water-Extractable Protein Using the Modified Lowry Method
ISO 2859–1 Sampling Procedures and Tables for Inspection by Attributes

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1 Please note that date of publication of standards are accurate at the time of publication of this document. With international standards always check the date of the latest edition.
Labelling of shipping cartons

*ISO 780*  
Packaging Pictorial Marking for Handling of Goods

**Quality management**

*ISO 9000:2005*  
Quality Management Systems Fundamentals and Vocabulary

*ISO 9001:2008*  
Quality Management Systems Requirements

*ISO 9004:2000*  
Quality Management Systems Guidelines for Performance Improvements

*ISO 13485:2003*  
Medical Devices Quality Management Systems Requirements for Regulatory Purposes

*ISO/IEC 17025:2005*  
General Requirements for the Competence of Testing and Calibration Laboratories

*ISO/IEC 1725:2005 Cor 1:2006*  

**Biocompatibility**

*ISO 10993 1:2003*  

*ISO 10993 5:1999*  
Biological Evaluation of Medical Devices. Part 5: Tests for in vitro Cytotoxicity

*ISO 10993 10:2002*  
Biological Evaluation of Medical Devices. Part 10: Tests for Irritation and Delayed-Type Hypersensitivity

## 2 Other publications

The following additional documents form part of the *WHO/UNFPA Specification* and may be cited in an Invitation to Bid or an order issued by a buyer.

- regulations on toxicity and tissue irritation (e.g. *U.S. Code of Federal Regulations* Title 21);

- freight classification;

- regulations for medical devices (if applicable);

- any other documents that are relevant under the law or regulations of the purchaser’s or the destination country;

ANNEX VII
LIST OF RESOURCE AGENCIES

Centers for Disease Control and Prevention
Programme Services and Evaluation Division of Reproductive Health
1600 Clifton Road N.E. (Mailstop K-22)
Atlanta, Georgia 30030, USA
http://www.cdc.gov/health/diseases.htm

Crown Agents Services, Ltd.
St. Nicolas House, St. Nicolas Road
Sutton, Surrey SM1 1EL, UK
http://www.crownagents.com/enquiries@crownagents.co.uk

Family Health International
P.O. Box 13950
Research Triangle Park, NC 27709, USA
http://www.fhi.org/publications@fhi.org

International Laboratory Accreditation Cooperation (ILAC)
NATA 7 Leeds Street
Rhodes, NSW, Australia
http://www.nata.asn.au

International Organization for Standardization (ISO)
ISO Central Secretariat
1, ch. de la Voie-Creuse
CP 56
1211 Geneva 20, Switzerland
http://www.iso.org/central@iso.org

John Snow, Inc.
1616 North Fort Myer Drive
Arlington, Virginia 22209, USA
http://deliver.jsi.com/dhome

Partners in Population and Development
P.O. Box 6020
Gulshan 1, Dhaka 1212
Bangladesh
http://www.partners-popdev.org/abtppd/abtppd_secretariat_contact.asp

Population Action International
1300 19th Street N.W., Second Floor
Washington, DC 20036, USA
http://www.populationaction.org/pai@popact.org

Population Services International
Procurement and Logistics
1120 19th Street N.W., Suite 600
Washington, DC 20036, USA
http://www.psi.org/publications@psi.org

Program for Appropriate Technology in Health (PATH)
Publications
P.O. Box 90922
Seattle, WA 98109, USA
http://www.path.org/publications@path.org

Reproductive Health Supplies Coalition
Coalition Secretariat
Rue Marie-Thérèse 21
1000 Brussels, Belgium
http://www.rhsupplies.org/secretariat@rhsupplies.org

UNAIDS
20 Avenue Appia
CH-1211 Geneva 27, Switzerland
http://www.unaids.org/unaids@unaids.org

UNFPA
Technical and Evaluation Division, Reproductive Health Branch
220 East 42nd Street
New York, NY 10017, USA
http://www.unfpa.org/procurement
http://www.unfpa.org/publications