



**INVITATION TO BID (ITB)
FOR
SUPPLY AND DISTRIBUTION OF
MALE LATEX CONDOMS (INTERNATIONAL)

OPEN TENDER METHOD**

Project Name: 'Continuation and Scale Up of HIV Prevention and Treatment Services
for Key Populations in Bangladesh'

ITB No. icddr,b/SCM/OTM/2024/404 dated 14 Mar 2024

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LETTER OF INVITATION

Dear Sir/Madam,

1. icddr,b is seeking qualified Bids for the *Supply and Distribution of male latex condoms* for its HIV/AIDS programme. Your company is hereby invited to submit your best Technical and Financial Bids for the requested male latex condoms.
2. Initially, the contract will be established for 3 years with successful bidder with a provision of extension of further periods, subject to budget availability and satisfactory performance and price competitiveness of the successful bidder.
3. To enable your company to submit a Bid, please read the following sections carefully:

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4. The Bid process will be conducted through a **One Stage TWO-envelope system**. Interested Bidders are requested to submit their **Technical Bid separately from their Financial Bid** containing price information. Bidders are requested to carefully read **Section I – Instructions to Bidders** where detailed instructions of the submission process are provided. It is the Bidder's responsibility to assure compliance with the submission process. If the

documentation or emails are not marked / submitted per the instructions, icddr,b will neither assume responsibility for the bid's misplacement or premature opening nor guarantee the confidentiality of the Bid process. Incorrect submissions might result in bid being declared invalid.

5. Bidders shall acknowledge receipt of the Invitation to Bid (ITB) through email to tender@icddr.org no later than 18 March 2024 and indicate whether or not a bid shall be submitted.
6. Any questions relating to the Bid process and/or to the attached documents shall be sent to: Sr. Manager, SCM at tender@icddr.org within 18 March 2024. Issues will be discussed in the pre-bid session (**online**) on **20 March 2024 at 2.00 pm** and responses will be given by 22 March 2024, if anything to clarify.
7. All documentation relating to the bid must be received by icddr,b no later than **01 April 2024 at 2.30 BST time** (GMT6+) in Chiller Building, icddr,b, Mohakhali, Dhaka. icddr,b will not accept bids after the closing deadline and as such no late bids will be accepted or recorded. **Combined technical and financial bid shall be rejected.** Bid will be opened in the same day at 3:00PM in presence of the tenderers, if any.
8. The purchaser (icddr,b) is a VAT and tax exempted organization. The Supply and distribution of condom will be guided by Global Fund (donor) Operation Policy and the donor's fund cannot be used by the purchaser for payment of Value Added Tax (VAT) and any other duties at the purchaser's country. The successful vendor may get the waiver of Advance Trade VAT (ATV) during custom clearance from the Government of Bangladesh upon apply.
9. Bid document will be available in the icddr,b website and the responses for the received query will be circulated via email to all pre-bid participants.
10. A checklist for the submission of required documents against the ITB has been attached at the end of the bid document to facilitate bidders in identifying the required documents to be submitted with the bid. Bidders are requested to fill up the check list and attached the filled-in checklist along with the bid during submission.
11. icddr,b looks forward to receiving your Bid and thank you in advance for your interest in icddr,b procurement opportunities. This letter is not to be construed in any way as an offer to contract with your company/institution.

Yours sincerely,



Mirza Muhammad Masud Rana,
Sr. Manager, SCM
icddr,b



SECTION I. INSTRUCTIONS TO TENDERERS (ITT)

A. INTRODUCTION

- | | | |
|--|-------|---|
| 1. Scope of Bid | 1.1 | The Purchaser, as specified in the Bid Data Sheet and in the Special Conditions of Contract (SCC), invites bids for the supply of Goods as specified in the Bid Data Sheet described in the Schedule of Requirements. |
| | 1.2 | The name and the identification no. of the Bid is stated in the Bid Data Sheet . |
| 2. Source of Funds | 2.1 | The Purchaser named in the Bid Data Sheet has received a grant (as identified with the grant number in the Bid Data Sheet and called a "grant" in these Bidding Documents) from the Global Fund toward the cost of the Project named in the Bid Data Sheet . The Purchaser intends to apply a part of the proceeds of this grant to eligible payments under the Contract for which these bidding documents are issued. |
| 3. Corrupt, Fraudulent, Collusive or Coercive Practices | 3.1 | The Purchaser requires that bidders, suppliers, contractors, and consultants under the Global Fund financed contracts observe the highest standard of ethics during the procurement and execution of such contracts. In pursuit of this policy, the Purchaser: |
| | (a) | defines, for the purposes of this provision, the terms set forth below as follows: |
| | (i) | "corrupt practice" means the offering, giving, promising to give, receiving, or soliciting, either directly or indirectly, to any officer or employee of a Procuring Entity or other public or private authority or individual, a gratuity in any form; employment or any other thing or service of value as an inducement with respect to an act or decision or method followed by a Procuring Entity in connection with a Procurement proceeding or contract execution; |
| | (ii) | "fraudulent practice" means a misrepresentation or omission of facts in order to influence a procurement process or the execution of a contract; |
| | (iii) | "collusive practice" means a scheme or arrangement between two or more bidders, with or without the knowledge of the purchaser, that is designed to arbitrarily reduce the number of Bids submitted or fix Bid prices at artificial, non-competitive levels, thereby denying a Procuring Entity the benefits of competitive price arising from genuine and open competition; or |
| | (iv) | "coercive practice" means harming or threatening to harm, directly or indirectly, Persons or their property to influence a decision to be taken in a Procurement proceeding or the execution of a Contract, and this will include creating obstructions in the normal submission process used for Bids. |
| | (b) | will reject a proposal for award if it determines that the Bidder recommended for award has, directly or through an agent, engaged in corrupt, fraudulent, collusive or coercive practices in competing for the Contract in question; |
| | (c) | will cancel the portion of the grant allocated to a contract if it determines at any time that representatives of the Purchaser |

or of a beneficiary of the grant engaged in corrupt, fraudulent, collusive or coercive practices during the procurement or the execution of that contract, without the purchaser having taken timely and appropriate action satisfactory to the Global Fund to remedy the situation;

- (d) will sanction a firm or individual, including declaring them ineligible, either indefinitely or for a stated period of time, to be awarded a Global Fund financed contract if it at any time determines that they have, directly or through an agent, engaged, in corrupt, fraudulent, collusive or coercive practices in competing for, or in executing, a Global Fund-financed contract; and
- (e) will have the right to require that a provision be included in Bidding Documents and in contracts financed by The Global Fund grant, requiring bidders, suppliers, contractors and consultants to permit the Global Fund to inspect their accounts and records and other documents relating to the Bid submission and contract performance and to have them audited by auditors appointed by the Global Fund.

3.2 Furthermore, bidders shall be aware of the provision stated in **Sub-Clauses 4.4** of ITT **and 23.1** of the General Conditions of Contract.

4. Eligible Bidders

- 4.1 Except as provided in ITT Sub-Clauses 4.2 and 4.3, this bidding process is open to qualified firms from all countries excluding the State of Israel, to participate and provide goods and services.
- 4.2 Firms of a member country may be excluded from bidding if:
 - (a) either: (i) as a matter of law or official regulation, the Purchaser's country prohibits commercial relations with that country, or (ii) the Purchaser's country prohibits any import of Goods from that country or any payments to persons or entities in that country.
 - (b) a firm has been engaged by the Purchaser that has been duly authorized to act on behalf of the Purchaser to provide consulting services for the preparation of the design, specifications, and other documents to be used for the procurement of the Goods described in these Bidding Documents.
- 4.3 Pursuant to ITT Sub-Clause 14.1, the Bidder shall furnish, as part of its bid, documents establishing, to the Purchaser's satisfaction, the Bidder's eligibility to bid.
- 4.4 Bidders shall provide such evidence of their continued eligibility satisfactory to the Purchaser.
- 4.5 Bidders and all parties constituting the Bidder shall not have a conflict of interest pursuant to :
 - Any staff of icddr,b who would have an interest, directly or indirectly, in a firm or individual that would bid against a tender notice issued by icddr,b must declare any relevant relationship with that firm or individual and consequently not participate in the ensuing proceedings.
 - All icddr,b employees or contractors involved in any procurement activity are required to declare any material

personal interest which may, or may be seen to affect their impartiality or judgement in respect to their involvement in the procurement process. Examples include close family members employed by a supplier or who have ownership in a company.

- An individual or a firm or its associates or affiliates, which would be involved in preparation of specifications for a particular tender, will not be eligible to participate in the ensuing procurement.
- Neither consultants (including their personnel and sub-consultants) nor any of their affiliates will be hired for any assignment that, by its nature, will be in conflict with another assignment of the consultants. (E.g. consultants hired to prepare the engineering design for an infrastructure project would not be engaged to prepare an independent assessment for the same project.) .

4.6 Bidders in its own name or its other names or also in the case of its Persons in different names, shall not be under a declaration of ineligibility for corrupt, fraudulent, collusive or coercive practices as stated under ITT Sub Clause 3.1.a

4.7 Bidders shall not be insolvent, be in receivership, be bankrupt, be in the process of bankruptcy, be not temporarily barred from undertaking business and it shall not be the subject of legal proceedings for any of the foregoing.

4.8 Bidders shall have fulfilled its obligations to pay taxes and social security contributions under the provisions of laws and regulations of the country of its origin. In the case of foreign Bidders, a certificate of competent authority in that country of which the Bidder is citizen shall be provided.

5. Eligible Goods and Services

5.1 Funds from grant are disbursed only on account of expenditures for Goods and Services, provided by nationals of, and produced in or supplied from, eligible source countries specified in **Bid Data Sheet**.

5.2 For purposes of this clause, the nationality of the bidder is distinct from the country from where the Goods and Services are supplied.

5.3 For purposes of this clause, (a) the term "Goods" includes any Goods that are the subject of this Invitation for Bids and (b) the term "Services" includes related services such as transportation, storage and distribution, insurance, commissioning, and training.

6. Documents Establishing Eligibility of Goods and Services and Conformity to Bidding Documents

6.1 Pursuant to ITT Clause 14, the Bidder shall furnish, as part of its bid, documents establishing, to the Purchaser's satisfaction, the eligibility of the Health Sector Goods and services to be supplied under the Contract.

6.2 The documentary evidence of the eligibility of the Goods and Services shall consist of a statement in the Price Schedule of the country of origin of the Goods and Services offered that shall be confirmed by a certificate of origin issued at the time of shipment.

6.3 The documentary evidence of conformity of the goods and services to the Bidding Documents may be in the form of

literature, drawings, and data and shall consist of:

- (a) a detailed description of the essential technical and performance characteristics of the Goods;
 - (b) an item-by-item commentary on the Purchaser's Technical Specifications demonstrating substantial responsiveness of the Goods and Services to those specifications, or a statement of deviations and exceptions to the provisions of the Technical Specifications;
 - (c) any other procurement specific documentation requirement as stated in the **Bid Data Sheet**.
- 6.4 Unless the **Bid Data Sheet** stipulates otherwise, the Goods to be supplied by the local manufacturer or the importer under the Contract, shall be registered with the relevant authority (Directorate of Drug Administration) in the Purchaser's country. The supplier/bidder who has already registered its Goods by the time of bidding shall submit a copy of the Registration Certificate along with its bid. In case the goods have not been registered before the bid submission, the successful bidder shall submit the NOC from the relevant authority (Directorate of Drug Administration) before the delivery of the goods.
- 6.5 For purposes of the commentary to be furnished pursuant to ITT Clause 6.3 (b) above, the Bidder shall note that technical specification, standards as well as references designated by the Purchaser in its Technical Specifications are intended to be followed.

7. Qualifications of the Bidder

- 7.1 The Bidder shall provide documentary evidence to establish to the Purchaser's satisfaction that:
- a) the Bidder has the financial, technical, and production capability necessary to perform the Contract, meets the qualification criteria specified in the **Bid Data Sheet**, and has a successful performance history in accordance with criteria specified in the **Bid Data Sheet**.
 - b) in the case of a Bidder who is not doing business within the Purchaser's country (or for other reasons will not itself carry out service/maintenance obligations), the Bidder is or will be (if awarded the Contract) represented by a local service/maintenance provider in the Purchaser's country equipped and able to carry out the Bidder's warehousing, distribution and transportation obligations prescribed in the Conditions of Contract and/or Technical Specifications.

8. Cost of Bidding

- 8.1 The Bidder shall bear all costs associated with the preparation and submission of its bid, and the Purchaser will in no case be responsible or liable for those costs, regardless of the conduct or outcome of the bidding process.

B. THE BIDDING DOCUMENT

- 9. Content of Bidding Documents**
- 9.1 The Bidding Documents are those stated below and should be read in conjunction with any addendum issued in accordance with ITT Clause 11.
- SECTION I. INSTRUCTIONS TO TENDERERS
 SECTION II. BID DATA SHEET
 SECTION III. GENERAL CONDITIONS OF CONTRACT
 SECTION IV. SPECIAL CONDITIONS OF CONTRACT
 SECTION V. BIDS AND CONTRACT FORMS
 SECTION VI. SCHEDULE OF REQUIREMENT
 SECTION VII. TECHNICAL SPECIFICATION OF MALE LATEX CONDOM
 SECTION VIII. ANNEXURES
- 9.2 The Purchaser may reject a bid if technical and financial document is not submitted in a separate envelope.
- 9.3 The Bidder is expected to examine all instructions, forms, terms, and specifications in the Bid Documents as well as addendum to Bid Documents.
- 10. Clarification of Bidding Documents**
- 10.1 A prospective Bidder requiring any clarification of the Bidding Documents shall contact the **Purchaser** in writing or by e-mail at the **Purchaser's** address **indicated in the Bid Data Sheet**. The **Purchaser will respond in writing to any request for clarification received**.
- 10.2 A purchaser is not obliged to answer any clarification received after that date requested under ITT Sub-clause 10.1.
- 10.3 The purchaser will respond in writing within five (5) working days of receipt of any such request for clarification received under ITT sub-clause 10.1.
- 10.4 Copies of the Purchaser's response shall be sent to all prospective Bidders including a description of the inquiry but without identifying its source.
- 10.5 To clarify issues and to answer questions on any matter arising in the Bid Document, the Purchaser may, if stated in the **Bid Data Sheet**, hold a **Pre-Bid Meeting** at the place, date and time as specified in the **Bid Data Sheet**. All Potential Bidders are encouraged to attend the meeting, if it is held.
- 10.6 Non-attendance at the Pre-Bid meeting will not be a cause for disqualification of a Bidder.
- 11. Addendum to Bidding Documents**
- 11.1 At any time prior to the deadline for submission of bids, the **Purchaser** may amend the Bidding Documents by issuing Addenda.
- 11.2 Any addendum thus issued shall be part of the Bidding Documents pursuant to ITT Sub-Clause 10.1 and shall be communicated in writing and/or to all purchasers of the Bidding Documents and will be binding on them. It will be assumed that the information contained in the amendment will have been considered by the Bidder in its bid.

- 11.3 To give prospective Bidders reasonable time in which to take the amendment into account in preparing their bids, the **Purchaser may extend**, at its discretion, the deadline for submission of bids, in which case, the purchaser will notify all Bidders in writing of the extended deadline pursuant to the ITT sub-clause 22.2.

C. PREPARATION OF BIDS

- 12. Language of Bid** 12.1 The bid, as well as all correspondence and documents relating to the bid exchanged by the Bidder and the Purchaser, shall be written in the language specified in the **Bid Data Sheet**. Supporting documents and printed literature furnished by the Bidder may be in another language provided they are accompanied by an accurate translation of the relevant passages in the language specified in the **Bid Data Sheet**, in which case, for purposes of interpretation of the Bid, the translation shall govern.
- 13. Documents Constituting the Bid** 13.1 The bid submitted by the Bidder shall comprise the following:
- a) A copy of the bid document duly sealed and signed by the bidder including all addendums (if any).
 - b) Original form of **bid security** in accordance with the provisions of ITT Sub-Clause 18 (Bid Security);
 - c) **Written power of attorney** authorizing the signatory of the bid to commit the Bidder or as mentioned in the **Bid Data Sheet**;
 - d) The completed **Specifications Submission and Compliance Sheet** as furnished in Section V: Bid and Contract Forms as stated under ITT Sub-Clause 6.3;
 - e) An **affidavit** confirming that the Bidder is not insolvent, in receivership or not bankrupt or not in the process of bankruptcy, not temporarily barred from undertaking their business for financial reasons and shall not be the subject of legal proceedings for any of the foregoing as stated under ITT Clause 4;
 - f) A **certificate** issued by the competent authority stating that the Bidder is a Tax payer having **valid Tax Identification Number (TIN) and VAT registration number** or in lieu any other document acceptable to the Purchaser demonstrating that the Bidder is a genuine Tax payer and has a VAT registration number as a proof of fulfillment of taxation obligations as stated under ITT Clause 4. In the case of foreign Bidders, a certificate of competent authority in that country of which the Bidder is citizen shall be provided;
 - g) The **country of origin** declarations, to establish the eligibility of the Goods and Related Services as stated under ITT Clause 6, in the Price Schedule for Goods and Related Services furnished in Section V: Bid and Contract Forms
 - h) **documentary evidence establishing to the Purchaser's satisfaction**, and in accordance with ITT Clause 7 that the

Bidder is qualified to perform the Contract if its bid is accepted.

- i) any other documentation as requested in the **Bid Data Sheet and any other sections of the bid document.**
- j) Duly filled-in **Bid Form and Price Schedule**, in accordance with the forms indicated in Section V; **Bid form and price schedule shall be part of financial proposal and shall be attached in Financial envelope.**

14. Bid Form 14.1 The Bidder shall complete the Bid Form and the Price Schedule furnished in the Bidding Documents, indicating the Goods to be supplied, a brief description of the Goods, their country of origin, quantity, and prices and shall be included the same in Financial envelope.

15. Bid Prices 15.1 Prices shall be quoted as specified in each Price Schedule included in Section V, Bid and Contract Forms. The disaggregation of price components is required solely for the purpose of facilitating the comparison of bids by the Purchaser. This shall not in any way limit the Purchaser's right to contract on any of the terms offered. In quoting prices, the Bidder shall be free to use transportation through carriers registered in any eligible country except Israel.

15.2 Prices shall be entered in the following manner:

- a) For Goods manufactured outside the Purchaser's Country, to be imported:
 - the price of the Goods, quoted DDP named place of destination (Governed by ICC Incoterms 2020), in the Purchaser's Country as specified in the **Bid Data Sheet**;
- b) The bidder offering the goods manufactured outside the Purchaser's Country, to be imported, ***must deploy a local agent / distributor for undertaking the logistic services (storage, distribution, transportation) as specified in the Bid Data Sheet***

15.3 Unless otherwise specified in the **Bid Data Sheet**, prices quoted by the Bidder shall be **fixed** as specified in Price Schedule during the Bidder's performance of the Contract and not subject to variation on any account. **A bid submitted with an adjustable price quotation will be treated as non-responsive and will be rejected, pursuant to ITT Clause 31.** If, however, in accordance with the **Bid Data Sheet**, prices quoted by the Bidder shall be subject to adjustment during the performance of the Contract, a bid submitted with a fixed price quotation will not be rejected, but the price will not be adjusted.

16. Currencies of Bid 16.1 Prices shall be quoted in the following currencies:
 (a) The Bidder may express the bid price entirely in the foreign currencies. If the Bidder wishes to be paid in a combination of different currencies, it must quote its price accordingly, but no more than three foreign currencies may be used or as mentioned in the **Bid Data Sheet**.

**17. Validity
Period
of
Bids**

- 17.1 Bids shall remain valid for the period stipulated in the **Bid Data Sheet** after the date of bid submission specified in ITT Clause 22. **A bid valid for a shorter period shall be rejected by the Purchaser as non-responsive.**
- 17.2 In justified exceptional circumstances, prior to expiry of the original bid validity period, the Purchaser may request **not later than ten (10) days** before the expiry date of the bid validity, compulsorily all the Bidders' consent to an extension of the period of validity of their Bids. The request and the responses thereto shall be made in writing.
- 17.3 Bidders consenting in writing to the request made by the Purchaser under ITT Sub-Clause 17.2 shall also correspondingly extend the validity of its Bid Security for twenty-eight (28) days beyond the new date for the expiry of Bid validity.
- 17.4 A Bidder may refuse the request without forfeiting its bid security and its offer will not be considered for evaluation. Except as provided in ITT Clause 17.3, a Bidder agreeing to the request will not be required or permitted to modify its bid, but will be required to extend the validity of its bid security for the period of the extension.

**18. Bid
Security**

- 18.1 If required, in the Bid Data Sheet, the Bidder shall furnish, as part of its bid, a bid security as specified in the **Bid Data Sheet**, or a Bid Securing Declaration. The amount of the Bid Security shall be as stipulated in the **Bid Data Sheet** in the currency of the Purchaser's country or equivalent US\$.
- 18.2 The Bid Security shall be in the form of Pay Order / Demand Draft /or an irrevocable bank guarantee in the format furnished in Section V: Bid and Contract Forms.
- 18.3 Bid Security shall payable promptly upon written demand by the Purchaser in the case of the conditions listed in sub-clause 18.8 being invoked.
- 18.4 The bid security shall remain valid for a period of 28 days beyond the validity period for the bid, and beyond any extension subsequently requested under Sub-clause 17.2.
- 18.5 Any bid not accompanied by an acceptable bid security shall be rejected by the Purchaser as non-responsive. The bid security of a joint venture must be in the name of the joint venture submitting the bid.
- 18.6 The bid securities of non-responsive Bidders will be returned immediately after the Evaluation Report has been approved by the Purchaser.
- 18.7 Bid securities of the responsive Bidders shall be returned only after the successful Bidder has submitted the performance security and signed the contract, that being even before the expiration of the validity period specified in Clause 17.

18.8 The bid security may be forfeited:

- a) if the Bidder withdraws its bid after the Bid opening but within the validity of the bid, except as provided in ITT Clauses 17 and 24.3; or
- b) in the case of a successful bidder, if the Bidder fails within the specified time limit to:
 - i) refuse to accept Notification of Award as stated under ITT Sub-Clause 39.1; or
 - ii) sign the contract as stated under ITT Sub-Clause 42.2; or
 - iii) furnish the required performance security as stated under ITT Sub-Clause 40.1; or does not accept the correction of the Bid price following correction of arithmetic errors as stated under ITT Sub-clause 32.1.

18.9 The Purchaser shall verify the authenticity of the Bid Security submitted by the successful Bidder by sending a written request to the branch of the bank issuing irrevocable Bank Guarantee in specified format /Pay Order/Bank Draft.

19.Alternative Proposals by Bidders

19.1 Alternative bids shall not be accepted.

20.Format and Signing of Bid

- 20.1 The bidder shall submit a hard copy of the bidding document with duly sealed and signed including the addendums issued (if any).
- 20.2 The Bidder shall prepare and submit an original (hard and soft) of the bid indicated in the **Bid Data Sheet**. In the event of any discrepancy between them, the original hard copy shall govern.

20.3 Any interlineations, erasures, or overwriting to correct errors made by the Bidder should be initialed by the person or persons signing the bid.

20.4 The Bidder shall furnish in the Bid Form (a sample of which is provided in the Sample Forms Section of the Bidding Documents) information regarding commissions or gratuities, if any, paid or to be paid to agents relating to this bid and to the execution of the Contract if the Bidder is awarded the Contract.

D. SUBMISSION OF BIDS

- 21. Sealing and Marking of Bids**
- 21.1 Bidders shall submit the bids as specified in the **Bid Data Sheet**.
- a) The bidder shall prepare two separate sealed envelopes for technical and financial bid clearly marked as "TECHNICAL" and "FINANCIAL". **The Purchaser may reject a bid if technical and financial document is not submitted in a separate envelope.**
 - b) The Bidder shall then enclose the original TECHNICAL and FINANCIAL offer in one master envelope marked as "ORIGINAL IN HARD" and one in soft (pdf) copy of the bid in accordance with ITT Clause 20.2, in separate sealed envelopes. Financial offer of the soft copy should be password protected and the password shall be shared to the email address mentioned at Bid Data Sheet.
- 21.2 The envelopes shall:
- (a) bear the **name and address of the Bidder** and its **local partner**;
 - (b) be addressed to the Purchaser at the address given in the **Bid Data Sheet**;
 - (c) bear the specific identification of this bidding process indicated in the **Bid Data Sheet**, the Invitation for Bids (ITB) title and number indicated in the **Bid Data Sheet**; and
 - (d) bear a statement "DO NOT OPEN BEFORE [date and time]" to be completed with the time and date specified in the Bid Data Sheet relating to ITT Sub-Clause 22.1.
- 21.3 If the envelope is not sealed and marked as required by ITT Sub-Clause 21.2, the Purchaser will assume no responsibility for the misplacement or premature opening of the bid.
- 22. Deadline for Submission of Bids**
- 22.1 Bids must be received by the Purchaser at the address specified in the **Bid Data Sheet** relating to ITT Sub-Clause 21.2 (b) no later than the time and date specified in the **Bid Data Sheet**.
- 22.2 The Purchaser may, at its discretion, extend the deadline for the submission of bids by amending the Bidding Documents in accordance with ITT Sub-Clause 11.3, in which case all rights and obligations of the Purchaser and Bidders previously subject to the deadline will thereafter be subject to the deadline as extended.
- 23. Late Bids**
- 23.1 Any bid received by the Purchaser after the deadline for submission of bids prescribed by the Purchaser in the **Bid Data Sheet** pursuant to ITT Clause 22 will be rejected and returned unopened to the Bidder.
- 24. Modification and Withdrawal of Bids**
- 24.1 The Bidder may modify or withdraw its bid after submission, provided that written notice of the modification, or withdrawal of the bids duly signed by an authorized representative, is received by the Purchaser **prior to the deadline prescribed**

for submission of bids.

- 24.2 The Bidder's modification shall be prepared, sealed, marked, and dispatched as follows:
- (a) The Bidder shall provide an original and the number of copies specified in the **Bid Data Sheet** of any modifications to its bid, clearly identified as such, in two inner envelopes duly marked "BID MODIFICATION-ORIGINAL" and "BID MODIFICATION-COPIES." The inner envelopes shall be sealed in an outer envelope, which shall be duly marked "BID MODIFICATION."
 - (b) Other provisions concerning the marking and dispatch of bid modifications shall be in accordance with ITT Sub-Clauses 21.2 and 21.3.
- 24.3 A Bidder wishing to withdraw its bid shall notify the Purchaser in writing prior to the deadline prescribed for bid submission. A withdrawal notice shall be received prior to the deadline for submission of bids. The notice of withdrawal shall:
- (a) be addressed to the Purchaser at the address named in the **Bid Data Sheet**,
 - (b) bear the specific identification of the bidding process (Contract name), the ITB title and ITB number, and the words "BID WITHDRAWAL NOTICE," and
 - (c) be accompanied by a written power of attorney authorizing the signatory of the withdrawal notice to withdraw the bid.
- 24.4 Bids requested to be withdrawn in accordance with ITT Sub-Clause 24.3, shall be returned unopened to the Bidders.
- 24.5 No bid may be withdrawn in the interval between the bid submission deadline and the expiration of the bid validity period specified in ITT Clause 17. Withdrawal of a bid during this interval may result in the forfeiture of the Bidder's bid security, pursuant to ITT Sub-Clause 18.8.

E. OPENING AND EVALUATION OF BIDS**25. Bid Opening**

- 25.1 The bidder will submit the bid in two envelop system as stated in ITT Clause no. 21.1. Bid opening session will only disclose the name of the bidders participated in the bid in presence of the bidders, if any. Only the bidders who obtains the required qualifying score in technical evaluation, shall be eligible for financial evaluation and those qualified bidder (s) will be invited during opening of financial proposal. Bidders' representatives shall sign a register as proof of their attendance.
- 25.2 Envelopes marked "WITHDRAWAL" shall be read out and the envelope with the corresponding bid shall not be opened but returned to the Bidder. No bid withdrawal notice shall be permitted unless the corresponding withdrawal notice is read out at bid opening. Envelopes marked "MODIFICATION" shall be read out and opened with the corresponding bid.
- 25.3 The Purchaser will prepare a bid opening statement at the end

of the opening session, including, as a minimum: the name of the Bidder, the name and signature of the bidder's representative, if any attend the opening session. The omission of a Bidder's signature on the opening statement shall not invalidate the content and effect of the documents.

26. Clarification of Bids

- 26.1 During evaluation of the bids, the Purchaser may, at its discretion, ask the Bidder for a clarification of its bid. The request for clarification and the response shall be in writing, and no change in the prices or substance of the bid shall be sought, offered, or permitted, except to correct arithmetic errors identified by the Purchaser in the evaluation of the bids, in accordance with ITT Sub-Clause 32.1.

27. Confidentiality

- 27.1 Information relating to the examination, clarification, evaluation, and comparison of bids, and recommendations for the award of a Contract shall not be disclosed to bidders or any other persons not officially concerned with such process until the notification of Contract award is made to all Bidders.
- 27.2 Any effort by the bidder to influence the Purchaser in the Purchaser bid evaluation, bid comparison, or contract award decisions may result in the rejection of the Bidder's bid.
- 27.3 From the time of bid opening to the time of Contract award, if any Bidder wishes to contact the Purchaser on any matter related to its bid, it should do so in writing.

28. Evaluation of Bids

- 28.1 Purchaser's Sourcing Evaluation Committee (SEC) shall examine, evaluate and compare Bids that are responsive to the mandatory requirements of Bid Documents in order to identify the successful Bidder. Bids shall be examined and evaluated only on the basis of the criteria specified in the Bid Document.

29. Evaluation Process

- 29.1 The SEC may consider a Bid as responsive in the Evaluation, only if it is submitted in compliance with the mandatory requirements set out in the Bid Document.
- 29.2 **The evaluation process shall begin immediately after Bid opening following below steps.**
- (a) **Preliminary examination (Screening Session)**
 - (b) **Technical evaluation (QCBS method will apply, Technical score-60 out of 100).**
 - (c) **Financial evaluation (QCBS method will apply, Financial score-40 out of 100)**
 - (d) **Post-qualifications of the highest scoring bidder (s) in combined technical and financial evaluation.**

30. Preliminary Examinations

- 30.1 Compliance, adequacy and authenticity of the documentary evidences for meeting the qualification criterion specified in the corresponding section of the Bid document shall have to be

preliminarily examined and verified. **Screening criteria for Preliminary examinations** will be as follows:

Sl. No.	Required Evidence
1	Principal/manufacturer confirmation as UNFPA prequalified (UNFPA Pre-qualification certificate)
2	Authorization of Local Agent as a representative of manufacturer
3	Submission of tender document with duly sealed and signed by Manufacturer
4	Separate Bid Submission for Technical & Financial proposal
5	Submission of Legal Documents for both manufacturer and the appointed agent
	1. Trade License or equivalent
	2. VAT Certificate or equivalent
	3. TIN Certificate or equivalent
6	Country of origin confirmation
7	Affidavit on financial Solvency for the agent and manufacturer
8	Power of Attorney to the agent
9	Bid Validity for 180 days, confirmed by the bidder
10	Compliance with technical specification as per WHO 2010 spec for male latex condom
11	Product registration from Local Authority / DGDA/NOC
12	Five Years Manufacturing Experience documents
13	Three years' Experience in distribution of health product
14	Minimum Production Capacity (≥ 50 m pcs) for manufacturer
15	Minimum Annual Turnover (≥ 0.6 MUS\$) for manufacturer

30.2 The SEC shall confirm that the above documents and information have been provided in the Bid and the completeness of the documents and compliance of instructions given in corresponding ITT Clauses shall be verified, failing which the Bid may be considered as non-responsive.

31. Technical Examinations & Responsiveness

31.1 Only Bids which are responsive in the preliminary examination shall be examined in this phase.

31.2 Technical evaluation will be conducted following QCBS (Quality and Cost based selection) method. The weightage of technical and financial score will be 60:40.

31.3 The SEC will examine the adequacy and authenticity of the

documentary evidences of the bidders and its local part, which may follow the order below:

Technical Evaluation:		
1. Capacity Assessment for Manufacturer		
i.	Quality Control Management	On-site Quality Management procedure
		Quality control laboratory facilities & services and range of tests conducted
ii.	Production and Financial Capacity	Number of Contracts ongoing
		Annual Production Capacity
		Annual Turnover
iii.	Reputation and Past Performance History	Contracts with UN or similar organization
		References Check
2. Capacity Assessment for Distribution agent		
i.	Agent’s reputation and past performance history	Number of Supply Contract with UN/ORG in BD & financial capacity for management of local part of the contract
ii.	Agent’s Warehouse Management	Warehouse Location & maintaining of WHO 2010 guideline for storing of Condom.
iii.	Agent’s Distribution Management	Existing Distribution channel/Distribution Plan

Minimum qualifying score for technical evaluation is 70% out of total technical score (60) for a bidder (s) to be eligible for financial evaluation.

31.4 The Purchaser may visit the premises of the Bidder and/or its local part as a part of the technical examination process.

32. Correction of Errors

32.1 Arithmetical errors will be rectified as follows:

- If there is a discrepancy between the unit price and the total price that is obtained by multiplying the unit price and quantity, the unit or subtotal price shall prevail.
- If there is a discrepancy between subtotals and the total price, the total price shall be corrected.
- If there is a discrepancy between words and figures, the amount in words will prevail.
- If a Bidder does not accept the correction of errors, its bid will be rejected and its bid security may be forfeited.

33. Conversion to Single Currency

33.1 To facilitate evaluation and comparison, the Purchaser will convert all bid prices expressed in the various currencies in which they are payable to either:

**34. Financial
Evaluation of Bid**

- (a) the currency of the Purchaser's country at the selling exchange rate established for similar transactions by the Central Bank or a commercial bank in the Purchaser's country. **Or**
 - (b) a currency widely used in international trade, such as U.S. Dollars, at the selling rate of exchange published in the international press for the amount payable in foreign currency; and at the selling exchange rate established for similar transactions by the Central Bank in the Purchaser's country for the amount payable in the currency of the Purchaser's country.
- 33.2 The currency selected for converting bid prices to a common base for the purpose of evaluation, along with the source and date of the exchange rate, are specified in the **Bid Data Sheet**.
- 34.1 The Purchaser's evaluation of a bid will exclude and not take into account:
- (a) in the case of Goods of foreign origin offered from abroad, customs duties and other similar import taxes that will be payable on the Goods if the contract is awarded to the Bidder; and
 - (c) any allowance for price adjustment during the period of execution of the Contract, if provided in the bid.
- 34.3 The SEC shall compare all responsive Bids by analysing the competitiveness of **supply and distribution price** to determine the highest scoring Bid, as stated under ITT Clause 34.

Financial evaluation

- i.** Price competitiveness for supply of Condom
- ii.** Price competitiveness for Distribution of condom

- 34.4 In the extremely unlikely event that there is a tie for the highest scoring bids, the bidder with the superior past performance with the Purchaser shall be selected, whereby factors such as delivery period, quality of Goods delivered, and performance in the previous contract with the client or with other national / international organizations could be taken into consideration.
- 34.5 In the event that there is a tie for the scoring and none of the Bidders has the record of past performance with the Purchaser, then the Bidder shall be selected, subject to firm confirmation through the Post-qualification process described in ITT Clause 35, after consideration as to whether the quality of Goods that is considered more advantageous by the end-users.

**35. Post-
qualification**

- 35.1 The Purchaser will determine to its satisfaction whether the Bidder that is selected as having submitted the highest scoring bid, is qualified to perform the Contract satisfactorily, in accordance with the criteria listed in ITT Sub-Clause 7.1 and any additional post-qualification criteria stated in the **Bid Data Sheet**.
- 35.2 The determination will evaluate the Bidder's financial, technical,

and production capabilities. It will be based on an examination of the documentary evidence of the Bidder's qualifications submitted by the Bidder, pursuant to ITT Sub-Clause 7.1, as well as other information the Purchaser deems necessary and appropriate.

- 35.3 The Purchaser shall contact the references given by Bidders about their previous Supply experiences to verify, if necessary, statements made by them in their Bid and to obtain the most up-to-date information concerning the Bidders.
- 35.4 The Purchaser may visit the premises of the Bidder as a part of the post-qualification process, if practical and appropriate, to verify information contained in its Bid. The objective of any visit shall be limited to a general and visual inspection of the Bidder's facilities and its plant and equipment, and there shall be no discussion concerning the Bid or its evaluation with the Bidder during such visit(s).
- 35.5 An affirmative post-qualification determination will be a prerequisite for award of the contract to the highest scoring bidder. In the event that the Bidder with highest scores fails the post-qualification, the Purchaser shall make a similar determination for the Bidder offering the next highest scoring bid and so on from the remaining responsive Bids, provided that,
- (a) such action shall only be taken if the evaluated costs of the Bid under consideration are acceptable to the Purchaser;
 - (b) when the point is reached whereby the evaluated costs of the remaining responsive Bids are significantly higher than that of the official estimate, or the market price, the Purchaser may act and may proceed for re-bidding, using a revised Bid Document designed to achieve a more successful result.

F. AWARD OF CONTRACT

- 36.Award Criteria** 36.1 Pursuant to ITT Clauses 31 and 34, the Purchaser will award the Contract to the Bidder whose bid has been determined to be the Highest Scored bid, provided further that the Bidder is determined to be qualified to perform the Contract satisfactorily, pursuant to ITT Clause 35.
- 37. Purchaser's Right to Accept Any Bid and to Reject Any / All Bids** 37.1 The Purchaser reserves the right to accept or reject any bid, or to annul the bidding process and reject all bids at any time prior to contract award, without thereby incurring any liability to the affected Bidder or Bidders.
- 38.Purchaser's Right to Vary Quantities at Time of Award** 38.1 The Purchaser reserves the right at the time of Contract award to increase or decrease, by the percentage indicated in the **Bid Data Sheet**, the quantity of goods and services beyond that originally specified in the Schedule of Requirements without any change in unit price or other terms and conditions. Final volume or quantity of the purchase as per the schedule of the contract may also vary as indicated in the **Bid Data Sheet**.
- 39.Notification of** 39.1 Prior to the expiration of the period of bid validity and within

Award

seven (7) working days of receipt of the approval of the award by the Approving Authority, the Purchaser will notify the successful Bidder in writing to be subsequently confirmed in writing that its bid has been accepted.

- 39.2 The NOA shall be accepted in writing by the successful Bidder within seven (7) working days from the date of issuance of NOA.
- 39.3 The NOA will constitute the formation of the Contract. Until a formal contract is signed, which shall become binding upon the furnishing of a Performance Security and the signing of the Contract by both parties.
- 39.4 Upon the successful Bidder's furnishing of the signed Contract Form and performance security pursuant to ITT Clause 40, the Purchaser will promptly notify each unsuccessful Bidder and will discharge its bid security, pursuant to ITT Clause 18.
- 39.5 If, after notification of award, a Bidder wishes to ascertain the grounds on which its bid was not selected, it should address its request to the Purchaser. The Purchaser will promptly respond in writing to the unsuccessful Bidder.

40. Performance Security

- 40.1 Within fourteen (14) days of the receipt of NOA from the Purchaser, the successful Bidder shall furnish the performance security in accordance with the Conditions of Contract. The Performance Security shall be in the form of irrevocable Bank Guarantee in the format available at Section V: Bid and Contract Form **shall be issued by an internationally reputable bank and it shall have correspondent bank located in Bangladesh, to make it enforceable.**
- 40.2 Failure of the successful Bidder to comply with the requirement of ITT Sub-Clause 40.1 shall constitute sufficient grounds for the annulment of the award and forfeiture of the bid security, in which event the Purchaser may make the award to the next highest scored bidder or call for new bids.
- 40.3 The proceeds of the Performance Security shall be payable to the Purchaser unconditionally upon first written demand as compensation for any loss resulting from the Supplier's failure to complete its obligations under the Contract.
- 40.4 The Performance Security shall be required to be valid until a date twenty-eight (28) days beyond the date of completion of the Supplier's performance obligations under the Contract, including any warranty obligations.
- 40.5 If under any circumstances date of completion of the Supplier's performance obligations under the Contract, including any warranty obligations is to be extended, the Performance Security shall correspondingly be extended for the extended period.

41. Authenticity of performance Security

- 41.1 The Purchaser shall verify the authenticity of the Performance Security submitted by the successful Bidder by sending a written request to the branch of the bank issuing irrevocable Bank Guarantee in specified format.

**42. Signing
Contract**

- 41.2 If the Performance Security submitted under ITT Clause 40.1 is not found to be authentic, the Purchaser shall proceed to take measures against the Bidder in accordance with ITT Sub-clause 40.2.
- of** 42.1 At the same time as the Purchaser issues the Notification of Award, the Purchaser shall send the draft Contract Agreement and all documents forming the Contract to the successful Bidder
- 42.2 Within twenty-eight (28) days of the issuance of Notification of Award, the successful Bidder and the Purchaser shall sign the contract provided that the Performance Security submitted by the Bidder is found to be genuine
- 42.3 If the successful Bidder fails to provide the required Performance Security, as stated under ITT Clause 40 or to sign the Contract , as stated under ITT Clause 42, the Purchaser shall proceed to award the Contract to the next highest scored bidder, and so on, by order of ranking or call for new bid pursuant to clause 35.5.

SECTION II. BID DATA SHEET

SECTION II. BID DATA SHEET

Instructions for completing the Bid Data Sheet are provided, as needed, in the notes in italics and under lined mentioned for the relevant ITT clauses.

ITT Clause	Amendments of, and Supplements to, Clauses in the Instruction to Bidders
	A. GENERAL
ITT 1.1	Name of Purchaser: Executive Director icddr,b 68, Shaheed Tajuddin Ahmed Sarani, Mohakhali, Dhaka-1212 or his or her authorised representatives or nominees
ITT 1.2	The Grant number, ITB no. and name of the Tender are: Grant no. BGD-H-ICDDRB-2464 ITT No. icddr,b/SCM/OTM/2024/404 dated 14 March 2024 Name of tender: Supply and Distribution of Male Latex Condoms. Scope of tender: Supply and Distribution of 37 million pieces of Male Latex Condoms up to the SC level as per icddr,b approved name and foil design.
ITT 2.1	Project Name: 'Continuation and Scale Up of HIV Prevention and Treatment Services for Key Populations in Bangladesh'
ITT 5.1	Eligible source countries: All countries except the state of Israel
ITT 6.4	The Government of Bangladesh has established product registration requirements for the Health Sector Goods. Successful Bidder is required to obtain and comply with authoritative and regulatory requirements. For the purpose of obtaining information about the requirements for registration of goods for local manufacturers and no objection certificate (NOC) for importers, bidders should contact: Directorate General of Drug Administration. Aushad Bhavan, Mohakhali, Dhaka-1212, Bangladesh. Tel : 8802 9880803, 9880864, 9880897, 9880924, Fax : 8802 9880854, E-mail: dgda.gov@gmail.com
ITT 7.1 (a)	Qualification criteria for the Bidders are : <ol style="list-style-type: none"> 1. UNFPA Pre-Qualification certification 2. 5 Years' experience in Condom Manufacturing and three years in distribution in local environment. 3. Required annual installed production capacity shall be at least 50 million pieces; 4. Required annual turnover shall be at least US Dollar 600,000 in any one of the last three years; and Note: If the bidder is a supplier, the requirements under ITT - 7.1(a) i shall be of the concerned manufacturer (s) and the requirement under ITT 7.1 (a) ii shall be of the bidder.

Documentary evidence in support of the required qualifications of the bidder to perform the Contract, shall be submitted:

(i) that, in the case of a Bidder that manufactures or otherwise produces (using ingredients supplied by primary manufacturers), the Bidder:

- a. is incorporated and registered in the country of manufacture of the Goods with valid Trade License, VAT and TIN Number;
- b. has authorized local agent/distributor (for goods produced abroad);
- c. has been licensed by the National Drug Regulatory Authority (NDRA) in the country of manufacture to supply the Goods;
- d. has manufactured and marketed the bidder to the specific goods covered by this Bidding Document, for at least five (5) years and three (3) years respectively;
- e. has received a satisfactory GMP certificate from the NDRA in the country of manufacture for condoms;
- f. possesses a valid WHO / UNFPA pre-qualification certificate for compliance in Quality Standard of product in line with the WHO 2010 Condoms Specifications;
- g. has on-site quality management procedure, quality control laboratory facilities and services and range of tests conducted;
- h. has necessary financial, Technical and production capacity to perform the contract in accordance with the qualification criteria mentioned above;
- i. Copies of audited financial statements and/or certified Annual Report for the last three fiscal years;
- j. Shall possess the required manufacturing experience and shall submit at least three (3) nos. performance certificate undertaken in last 5 years and a list of current contracts in hand (commitment). The experience certificate shall be in the letterhead of the customer and shall mention the contract quantity, contract value, year of execution. The list of current commitment shall be supported by purchase order or the contract issued by the customer in favour of the bidder.
- k. the bidder shall provide proof of experience with and knowledge of modes of packing, distribution and transportation of condoms under logistical and climatic conditions similar to the purchaser's country.

ii) That, in the case of a Bidder offering to supply Goods under the package that the Bidder does not manufacture or otherwise produce, shall submit all the **documents mentioned above including the following:**

- (a) that the Bidder has been duly authorized by a manufacturer of the Goods that meets the criteria under (i) above to supply the Goods in the Purchaser's country;

B. THE BIDDING DOCUMENTS

ITT 10.1	For the purpose of providing Bid documents and their clarification, Purchaser's address is: Attention: Director, Supply Chain & Facilities Management Address: icddr,b 68, Shaheed Tajuddin Ahmed Sarani, Mohakhali, Dhaka-1212. Telephone: (+88 02) 9827001-10 Facsimile number: 880-2-8811686 Electronic mail address: tender@icddr.org Online Pre-bid meeting will be held on 20th March 2024 at 2:00 PM (GMT+6) Meeting link: Microsoft Teams Join the meeting now Meeting ID: 474 864 702 01 Passcode: mH3kMj
ITT 10.5	

C. PREPARATION OF BIDS

ITT 12.1	The language of all correspondence and documents related to the bid is English .
ITT 13.1	In addition to the documents stated in Paragraphs 13.1 (a) through (i), the following documents shall be included with the Bid: <ul style="list-style-type: none"> (a) Documentary evidence for qualifying WHO/UNFPA prequalification scheme for supplier/manufacture of male latex condom; (b) Documentary evidence of production lot compliance testing in accordance with WHO/UNFPA 2010 condom specifications carried out by WHO accredited testing laboratory not more than two years old in case of supplier/manufacture of male latex condom; (c) Bidders who are not primary manufacturers should provide documentary evidence that their product conforms to the quality standards of the primary manufacturer and they have the capacity to supply the specified quantities. A "primary manufacturer" is defined as a company that performs all the manufacturing and formulating operations needed to produce the requested goods in their appropriate forms, including processing, blending, formulating, filling, packing, labeling, and quality testing. The Bidder shall furnish a certificate from the competent NDRA in the country of manufacture that the manufacturer is licensed to manufacture the Goods offered, if applicable.
ITT 13.1(d)	A Power of Attorney authorizing the signatory to sign the Bid on behalf of the Bidder from competent authority must be provided. If the signatory of the Bid is duly authorized by the memorandum and articles of association or the constitution of the Bidder, certified copy of the relevant sections of the said constitution should be provided. In case, the Bidder is a sole-proprietorship/partnership firm, necessary affidavit should be

	provided. Otherwise the Bid may be rejected.
ITT 15.2 (a)	Prices for Goods offered from abroad shall be quoted as: DDP. The SCs shall be as per Annex- B: List of distribution sites. These sites may be increased or decreased as per the discretion of the purchaser based on the actual requirements.
ITT 15.2 (b)	<p>For agents and service facilities in the purchaser's country: If a foreign bidder engages an agent in the purchaser's country, the agency commission payable to the agent shall be indicated in the space provided in the price schedule. They also will be required to give following details in the bid along with an authorization letter:</p> <ul style="list-style-type: none"> (i) the name and address of the local agent; (ii) what services the agent renders; (iii) trade license; (iv) proof of financial soundness; (v) Details of the Storage facilities in the purchaser's country including the address and storage condition shall be provided with the bid. Storage condition shall be as per WHO guideline for male latex condom. Storage facilities shall have the capacity to preserve condom for at least one quarter as per WHO guideline. The purchaser will do the condom sampling for third party QC from the local storage facilities. (vi) has the access with any transport media to deliver up to health service delivery points and the proposed distribution plan shall be submitted with the bid.
ITT 15.5	Prices quoted by the Bidder shall be fixed for entire contract period.
ITT 16.1 (a)	Bidder's supplying goods from outside the purchaser's country shall quote prices in USD and shall receive payment in USD.
ITT 17.1	The Bid validity period shall be 180 (one hundred Eighty) days after the deadline of bid submission, as specified in ITT Clause 22.
ITT 18.1	No bid security will be required in participating the bid.
ITT 20.2	Required number of copies of the bid: One original (in hard and electronic copy in PDF in a form of portable media.

D. SUBMISSION OF BIDS

ITT 21.1 (b)	Password for soft copy of the financial offer should be sent to the email id ershad@icddrb.org
ITT 21.2 (b)	For <u>Tender submission purposes</u> only, the Purchaser's address is: Attention: Director, Supply Chain & Facilities Management Address: icddr,b 68, Shaheed Tajuddin Ahmed Sarani, Mohakhali, Dhaka-1212.
ITT 22.1	The deadline for the submission of Tenders is: Time & Date: 1st April 2024; 2:30 PM Address: Chiller Building icddr,b 68, Shaheed Tajuddin Ahmed Sarani, Mohakhali, Dhaka-1212.
ITT 24.1	No bid shall be modified subsequent to the deadline for submission of bids.

E. BID OPENING AND EVALUATION

ITT 25.1	The Tender opening shall take place at: Venue: Chiller Building Address: icddr,b 68, Shaheed Tajuddin Ahmed Sarani, Mohakhali, Dhaka-1212. Time & Date: 1st April 2024; 3:00 PM
ITT 33.2	For evaluation and comparison purpose, the SEC shall convert all Bid prices expressed in the amounts in various currencies into an amount in USD on the grant currency rate
ITT 31.4, ITT 35	The Purchaser may visit Manufacturer /Local Agent office before signing of Contract.

F. AWARD OF CONTRACT

ITT 38.1	Percentage for increase or decrease of quantity of Goods either during contract award or during the execution of the signed contract: 25% (twenty five percent)
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SECTION III. GENERAL CONDITIONS OF CONTRACT

GENERAL CONDITIONS OF CONTRACT

- 1. Definitions** 1.1 In this Contract, the following terms shall be interpreted as indicated:
- (a) "The Contract" means the agreement entered into between the Purchaser and the Supplier, as recorded in the Contract Form for duration as specified **in the SCC**, signed by the parties, including all attachments and appendices thereto and all documents incorporated by reference therein.
 - (b) "The Contract Price" means the price payable to the Supplier under the Contract for the full and proper performance of its contractual obligations.
 - (c) "Day" means calendar day.
 - (d) "Effective Date" means the date on which this Contract becomes effective pursuant to GCC Clause 6.2.
 - (e) "Eligible Country" means the countries and territories eligible for participation in procurements in People's Republic of Bangladesh
 - (f) "End User" means the organization(s) where the goods will be used, as **named in the SCC**.
 - (g) "GCC" means the General Conditions of Contract contained in this section.
 - (h) "The Goods" means all of the pharmaceuticals including nutritional supplement and oral and injectable forms of contraception, vaccines, and condoms that the Supplier is required to supply to the Purchaser under the Contract.
 - (i) "The Purchaser" means the organization purchasing the Goods, as **named in the SCC**.
 - (j) "The Purchaser's country" is the country **named in the SCC**.
 - (k) "Registration Certificate" means the certificate of registration or other documents in lieu thereof establishing that the Goods supplied under the Contract are registered for use in the Purchaser's country in accordance with the Applicable Law.
 - (l) "SCC" means the Special Conditions of Contract.
 - (m) "The Services" means those services ancillary to the supply of the Goods, such as storage, distribution, transportation and insurance, and any other incidental services, such as provision of technical assistance, training, and other such obligations of the Supplier covered under the Contract.
 - (n) "The Site", throughout these bidding documents, where applicable, means the place or places **named in the SCC**.
 - (o) "The Supplier" means the individual or firm supplying the Goods and Services under this Contract, as **named in the SCC**.
 - (p) "Writing" means any type-written, or printed communication, including e-mail, telex, cable, and facsimile transmission.
- 2. Application** 2.1 These General Conditions shall apply to the extent that they are not superseded by provisions of other parts of the Contract.
- 3. Country of Origin** 3.1 All Goods and Services supplied under the Contract shall have their origin in the countries and territories eligible under the rules of the People's Republic of Bangladesh, as further **elaborated**

- in the SCC.**
- 3.2 For purposes of this Clause, "origin" means the place where the Goods were mined, grown, or produced, or from which the Services are supplied. Goods are produced when, through manufacturing, processing, or substantial and major assembly of components, a commercially recognized new product results that is substantially different in basic characteristics or in purpose or utility from its components.
- 3.3 The origin of Goods and Services is distinct from the nationality of the Supplier.
- 4. Standards and Specifications**
- 4.1 The Goods supplied under this Contract shall conform to the standards mentioned in the Technical Specifications as well as **SCC** and, when no applicable standard is mentioned, to the authoritative standards appropriate to the Goods' country of origin. Such standards shall be the latest issued by the concerned institution.
- 5. Use of Contract Documents and Information; Inspection and Audit by the Purchaser**
- 5.1 The Supplier shall not, without the Purchaser's prior written consent, disclose the Contract, or any provision thereof, or any specification, plan, drawing, pattern, sample, or information furnished by or on behalf of the Purchaser in connection therewith, to any person other than a person employed by the Supplier in the performance of the Contract. Disclosure to any such employed person shall be made in confidence and shall extend only so far as may be necessary for purposes of such performance.
- 5.2 The Supplier shall not, without the Purchaser's prior written consent, make use of any document or information enumerated in GCC Sub-Clause 5.1 except for purposes of performing the Contract.
- 5.3 Any document, other than the Contract itself, enumerated in GCC Sub-Clause 5.1 shall remain the property of the Purchaser and shall be returned (all copies) to the Purchaser on completion of the Supplier's performance under the Contract if so required by the Purchaser.
- 5.4 The Supplier shall permit the Purchaser or the Global Fund to inspect the Supplier's accounts and records relating to the performance of the Contract and to have them audited by auditors appointed by the above, if so required.
- 6. Certification of Goods in Accordance with Laws of the Purchaser's Country**
- 6.1 If required under the Applicable Law, Goods supplied under the Contract shall be registered for use in the Purchaser's country in case of local manufacturers; otherwise No Objection Certificate (NOC) during import of goods by the Local Agent is required.
- 6.2 Unless otherwise specified in the SCC, the Contract shall become effective on the date ("the Effective Date") when both the party has signed the contract.
- 6.3 If thirty (30) days, or such longer period **specified in the SCC**, elapse from the date of Contract signing and the Contract has not become effective pursuant to Sub-Clause 6.2 above, then either party may, by not less than seven (7) days' written notice to the other party, declare this Contract null and void. In such

event, the Supplier's performance security shall be promptly returned.

7. Patent Rights 7.1

The Supplier shall indemnify the Purchaser against all third-party claims of infringement of patent, trademark, or industrial design rights arising from use of the Goods or any part thereof in the Purchaser's country.

8. Performance Security 8.1

Within Fourteen (14) days of receipt of the notification of Contract award, the successful Bidder shall furnish to the Purchaser the performance security in the amount **specified in the SCC.**

8.2 The proceeds of the performance security shall be payable to the Purchaser as compensation for any loss resulting from the Supplier's failure to complete its obligations under the Contract.

8.3 The performance security shall be denominated in the currency of the Contract, and shall be in one of the following forms:

(a) a bank guarantee or an irrevocable letter of credit issued by a reputable bank located in the Purchaser's country or abroad, acceptable to the Purchaser, in the format provided in the Bidding Documents or another format acceptable to the Purchaser;

or

(b) a cashier's or certified check.

8.4 If under any circumstances date of completion of the Supplier's performance obligations under the Contract, including any warranty obligations is to be extended, the Performance Security shall correspondingly be extended for the extended period.

8.5 The Performance Security shall be required to be valid until a date twenty-eight (28) days beyond the date of completion of the Supplier's performance obligations under the Contract, including any warranty obligations.

8.6 The performance security will be discharged by the Purchaser and returned to the Supplier not later than forty-five (45) days following the date of completion of the Supplier's performance obligations under the Contract, including any warranty obligations, unless **specified otherwise in the SCC.**

9. Inspections and Tests 9.1

The Purchaser or its representative shall have the right to inspect and/or to test the Goods to confirm their conformity to the Contract specifications. The **SCC** and the Technical Specifications shall specify what inspections and tests the Purchaser requires and where they are to be conducted. The Purchaser shall notify the Supplier in writing, in a timely manner, of the identity of any representatives retained for these purposes

(a) Upon receipt of the Goods at the warehouse of the supplier / its authorized agent at the destination country, the Purchaser's representative shall inspect the Goods or part of the Goods to ensure that they conform to the condition of the Contract.

(b) To ensure the quality of the goods, the purchase will hire independent testing laboratory for conducting the testing of the products as per WHO 2010 / ISO4074. For conducting the testing, the Purchaser will do the random sampling of

the products and send to its nominated QC laboratories for conducting the tests.

- (c) The Purchaser reserve the right to contests the test report issued by the independent QC lab if there is any major deviation (s) found between the in-house Certificate of Analysis issued by/from the supplier factory and the independent QC lab.
- (c) The Purchaser will share the distribution schedule with the Supplier or its authorized distribution agent upon receipt of the satisfactory test report from the independent testing laboratory.

- 9.2 Where the Supplier contests the validity of the rejection by the Purchaser or his representative, of any inspection as required by 9.1 above conducted before shipment or at ultimate destination, whether based on product or packing grounds, a sample drawn jointly by the Supplier and Purchaser or his or her representative and authenticated by both, will be forwarded for umpire analysis within four weeks of the time the Supplier contests to an independent agency mutually agreed by the Purchaser and Supplier. The umpire's finding, which will be promptly obtained, will be final and binding on both parties. The cost of umpire analysis will be borne by the losing party.

10. Packing

- 10.1 The Supplier shall provide such packing of the Goods (CE standard) as is required to prevent their damage or deterioration during transit to their final destination, as indicated in the Contract. The packing shall be sufficient to withstand, without limitation, rough handling during transit and exposure to extreme temperatures, salt, and precipitation during transit and open storage. Packing case size and weights shall take into consideration, where appropriate, the remoteness of the Goods' final destination and the absence of heavy handling facilities at all points in transit.

11. Delivery and Documents

- 11.1 Delivery of the Goods shall be made by the Supplier in accordance with the terms specified in the Schedule of Requirements. The details of shipping and/or other documents to be furnished by the Supplier are **specified in the SCC.**
- 11.2 For purposes of the Contract, "DDP," "EXW," "FOB," "FCA," "CIF," "CIP," and other trade terms used to describe the obligations of the parties shall have the meanings assigned to them by the current edition of *Incoterms* published by the International Chamber of Commerce, Paris.
- 11.3 Documents to be submitted by the Supplier are **specified in the SCC.** *Incoterms* provides a set of international rules for the interpretation of the more commonly used trade terms.

12. Insurance

- 12.1 The Goods supplied under the Contract shall be fully insured in a freely convertible currency against loss or damage incidental to manufacture or acquisition, transportation, storage, and delivery in the manner **specified in the SCC.**

13. Transportation

- 13.1 Where the Supplier is required under the Contract to transport the Goods DDP to a specified place of destination within the Purchaser's country, defined as the Site, transport to such place of destination in the Purchaser's country, including insurance and

storage, as shall be specified in the Contract, shall be arranged by the Supplier at its own cost.

14. Incidental Services

- 14.1 The Supplier shall provide such incidental services, if any, as are **specified in the SCC.**
- 14.2 Prices charged by the Supplier for incidental services, if not included in the Contract Price for the Goods, shall be agreed upon in advance by the parties and shall not exceed the prevailing rates charged to other parties by the Supplier for similar services.

15. Warranty

- 15.1 All goods must be of fresh manufacture and must bear the dates of manufacture and expiry. The Supplier further warrants that all Goods supplied under the Contract will have remaining a minimum shelf life as mentioned in the **Section VII: Technical specification of the goods.**
- 15.2 The Purchaser shall have the right to make claims under the above warranty for three months after the Goods have been delivered to the final destination indicated in the Contract. Upon receipt of a written notice from the Purchaser, the Supplier shall, with all reasonable speed, replace the defective Goods without cost to the Purchaser. The Supplier will be entitled to remove, at his own risk and cost, the defective Goods once the replacement Goods have been delivered.
- 15.3 In the event of a dispute by the Supplier, a counter analysis will be carried out on the manufacturer's retained samples by an independent neutral laboratory agreed by both the Purchaser and the Supplier. If the counter analysis confirms the defect, the cost of such analysis will be borne by the Supplier as well as the replacement and disposal of the defective goods. In the event of the independent analysis confirming the quality of the product, the Purchaser will meet all costs for such analysis.
- 15.4 If, after being notified that the defect has been confirmed pursuant to GCC Sub-Clause 15.2 above, the Supplier fails to replace the defective Goods within the period **specified in the SCC**, the Purchaser may proceed to take such remedial action as may be necessary, including removal and disposal, at the Supplier's risk and expense and without prejudice to any other rights that the Purchaser may have against the Supplier under the Contract. The Purchaser will also be entitled to claim for storage in respect of the defective Goods for the period following notification and deduct the sum from payments due to the Supplier under this Contract.
- 15.5 **Recalls.** In the event any of the Goods are recalled, the Supplier shall notify the Purchaser within fourteen (14) days, providing full details of the reason for the recall and promptly replace, at its own cost, the items covered by the recall with Goods that fully meet the requirements of the technical Specification and arrange for collection or destruction of any defective Goods. If the Supplier fails to fulfill its recall obligation promptly, the Purchaser will, at the Supplier's expense, carry out the recall.
- 15.6 Performance Security under GCC Clause no 8 shall only be released after the lapse of the warranty period at the end of contract period, provided that the goods supplied are free from patent and latent

defects and all the conditions imposed under the contract have been fully met.

(a) A patent defect, which is one that is apparent to the buyer on normal observation. It is an apparent or obvious defect. For example, a ball pen that does not write is patently defective.

(b) A latent defect, which is one that is not apparent to the buyer by reasonable observation. A latent defect is "hidden" or one that is not immediately determinable. For example, a ball pen that writes 0.75 kilometers instead of the expected 1.5 kilometres has a latent defect.

16. Payment

16.1 The method and conditions of payment to be made to the Supplier under this Contract shall be **specified in the SCC**.

16.2 The Supplier's request(s) for payment shall be made to the Purchaser in writing, accompanied by an invoice describing, as appropriate, the Goods delivered and Services performed, and by documents submitted pursuant to GCC Clause 11, and upon fulfillment of other obligations stipulated in the Contract.

16.3 Payments shall be made promptly by the Purchaser, as indicated in the **SCC** after submission of an invoice or claim by the Supplier.

16.4 The currency or currencies in which payment is made to the Supplier under this Contract shall be **specified in the SCC**.

17. Prices

17.1 Prices charged by the Supplier for Goods delivered and Services performed under the Contract shall not vary from the prices quoted by the Supplier in its bid, with the exception of any price adjustments **authorized in the SCC** or in the Purchaser's request for bid validity extension, as the case may be.

18. Change Orders

18.1 The Purchaser may at any time, by a written order given to the Supplier pursuant to GCC Clause 32, make changes within the general scope of the Contract in any one or more of the following:

- (a) specifications, where Goods to be furnished under the Contract are to be specifically manufactured for the Purchaser;
- (b) the method of shipment or packing;
- (c) the place of delivery; and/or
- (d) the Services to be provided by the Supplier.
- (e) mode of payments

18.2 If any such change causes an increase or decrease in the cost of, or the time required for, the Supplier's performance of any provisions under the Contract, an equitable adjustment shall be made in the Contract Price or delivery schedule, or both, and the Contract shall accordingly be amended. Any claims by the Supplier for adjustment under this clause must be asserted within **thirty (30)** days from the date of the Supplier's receipt of the Purchaser's change order.

19. Contract Amendments

19.1 Subject to GCC Clause 18, no variation in or modification of the terms of the Contract shall be made except by written amendment signed by the parties.

20. Renewal of the contract

20.1 The contract may be renewed as per the mutual agreement between the Purchaser and the Supplier for the duration specified in the **SCC**.

21. Assignment

21.1 The Supplier shall not assign, in whole or in part, its obligations to any other party to perform under this Contract, except with

- the Purchaser's prior written consent.
- 22. Delays in the Supplier's Performance**
- 22.1 Delivery of the Goods and performance of Services shall be made by the Supplier in accordance with the time schedule prescribed by the Purchaser in the Schedule of Requirements.
- 22.2 If at any time during performance of the Contract, the Supplier or its subcontractor(s) should encounter conditions impeding timely delivery of the Goods and performance of Services, the Supplier shall promptly notify the Purchaser in writing of the fact of the delay, its likely duration, and its cause(s). As soon as practicable after receipt of the Supplier's notice, the Purchaser shall evaluate the situation and may at its discretion extend the Supplier's time for performance, with or without liquidated damages, in which case the extension shall be ratified by the parties by amendment of Contract.
- 22.3 Except as provided under GCC Clause 25, a delay by the Supplier in the performance of its delivery obligations shall render the Supplier liable to the imposition of liquidated damages pursuant to GCC Clause 23, unless an extension of time is agreed upon pursuant to GCC Clause 22.2 without the application of liquidated damages.
- 23. Liquidated Damages**
- 23.1 Subject to GCC Clause 25, if the Supplier fails to deliver any or all of the Goods or to perform the Services within the period(s) specified in the Contract, the Purchaser shall, without prejudice to its other remedies under the Contract, deduct from the Contract Price, as liquidated damages, a sum equivalent to the percentage **specified in the SCC** of the delivered price of the delayed Goods or unperformed Services for each week or part thereof of delay until actual delivery or performance, up to a maximum deduction of the percentage **specified in the SCC**. Once the maximum is reached, Purchaser may consider termination of the Contract pursuant to GCC Clause 24.
- 24. Termination for Default**
- 24.1 The Purchaser, without prejudices to any other remedy for breach of Contract, by written notice of default sent to the Supplier, may terminate this Contract in whole or in part:
- (a) if the Supplier fails to deliver any or all of the Goods within the period(s) specified in the Contract, or within any extension thereof granted by the Purchaser pursuant to GCC Clause 22; or
 - (b) if the Goods do not meet the Technical Specifications stated in the Contract; or
 - (c) if the Supplier fails to provide any registration or other certificates in respect of the Goods within the time specified in the Special Conditions.
 - (d) if the Supplier, in the judgment of the Purchaser, has engaged in corrupt, fraudulent, collusive or coercive practices in competing for or in executing the Contract.
 - (e) if the Supplier fails to perform any other obligation(s) under the Contract.
- 24.2 In the event the Purchaser terminates the Contract in whole or in part, pursuant to GCC Clause 24.1, the Purchaser may procure, upon such terms and in such manner as it deems appropriate, Goods or Services similar to those undelivered, and the Supplier shall be liable to the Purchaser for any excess costs for such similar Goods or Services. However, the Supplier shall continue performance of the Contract to the extent not terminated.

25. Force Majeure

- 25.1 Notwithstanding the provisions of GCC Clauses 22, 23, and 24, the Supplier shall not be liable for forfeiture of its performance security, liquidated damages, or termination for default if and to the extent that its delay in performance or other failure to perform its obligations under the Contract is the result of an event of Force Majeure.
- 25.2 For purposes of this clause, "Force Majeure" means an event beyond the control of the Supplier and not involving the Supplier's fault or negligence and not foreseeable. Such events may include, but are not restricted to, acts of the Purchaser in its sovereign capacity, wars or revolutions, fires, floods, epidemics, quarantine restrictions, exceptional economic events and freight embargoes.
- 25.3 If a Force Majeure situation arises, the Supplier shall promptly notify the Purchaser in writing of such condition and the cause thereof. Unless otherwise directed by the Purchaser in writing, the Supplier shall continue to perform its obligations under the Contract as far as is reasonably practical and shall seek all reasonable alternative means for performance not prevented by the Force Majeure event.

26. Termination for Insolvency

- 26.1 The Purchaser may at any time terminate the Contract by giving written notice to the Supplier if the Supplier becomes bankrupt or otherwise insolvent. In this event, termination will be without compensation to the Supplier, provided that such termination will not prejudice or affect any right of action or remedy that has accrued or will accrue thereafter to the Purchaser.

27. Termination for Convenience

- 27.1 The Purchaser, by written notice sent to the Supplier, may terminate the Contract, in whole or in part, at any time for its convenience. The notice of termination shall specify that termination is for the Purchaser's convenience, the extent to which performance of the Supplier under the Contract is terminated, and the date upon which such termination becomes effective.
- 27.2 Any of the following circumstances may constitute sufficient grounds to terminate a contract for conveniences:
- (a) If physical and economic conditions have significantly changed so as to render the contract no longer economically, financially or technically feasible, as determined by the Purchaser;
 - (b) The Purchaser has determined the existences of conditions that make contract implementation impractical and/or unnecessary, such as, but not limited to, fortuitous event/s, change in laws and government policies;
 - (c) Funding for the contract has been withheld or reduced;
 - (d) Any circumstances analogous to the foregoing.
- 27.3 The Goods that are complete and ready for shipment within thirty (30) days after the Supplier's receipt of notice of termination shall be accepted by the Purchaser at the Contract terms and prices. For the remaining Goods, the Purchaser may elect any one of the followings at its sole discretion:
- (a) to have any portion completed, packed, where required quality test done but not ready for shipment within 30 days of the notice of termination are to be delivered and paid at the Contract terms and prices; or

28. Procedure for Termination of Contract

(b) to cancel the remainder and pay to the Supplier an agreed compensation amount for completed/partially completed Goods and Services only.

The purchaser shall not be liable for any of the remaining materials in the form of raw ingredients, semi-finished materials, tools, equipment, services etc. procured by the supplier for executing the said contract other than those mentioned above.

28.1 The following provisions shall govern the procedures for termination of this contracts stated under GCC clause 24, 26 and 27:

(a) Upon receipt of a written report of acts or causes which may constitute ground(s) for termination as aforementioned, or upon its own initiative, the Purchaser shall, within a period of seven (7) calendar days, verify the existence of such ground(s) and cause the execution of a Verified Report, with all relevant evidence attached;

(b) Upon review, the Purchaser shall terminate this Contract only by a written notice to the Supplier conveying the termination of this Contract. The notice shall state:

(i) that this Contract is being terminated for any of the ground(s) afore-mentioned, and a statement of the acts that constitute the ground(s) constituting the same;

(ii) the extent of termination, whether in whole or in part;

(iii) an instruction to the Supplier to show cause as to why this Contract should not be terminated; and special instructions of the Purchasers, if any;

29. Settlement of Disputes

29.1 If any dispute or difference of any kind whatsoever shall arise between the Purchaser and the Supplier in connection with or arising out of the Contract, the parties shall make every effort to resolve amicably such dispute or difference by mutual consultation.

29.2 If, after thirty (30) days, the parties have failed to resolve their dispute or difference by such mutual consultation, then either the Purchaser or the Supplier may give notice to the other party of its intention to commence arbitration, as hereinafter provided, as to the matter in dispute, and no arbitration in respect of this matter may be commenced unless such notice is given.

29.3 Any dispute or difference in respect of which a notice of intention to commence arbitration has been given in accordance with this Clause shall be finally settled by arbitration. Arbitration may be commenced prior to or after delivery of the Goods under the Contract.

29.4 Arbitration proceedings shall be conducted in accordance with the rules of procedure **specified in the SCC.**

29.5 Notwithstanding any reference to arbitration herein,

(a) the parties shall continue to perform their respective obligations under the Contract unless they otherwise agree; and

(b) the Purchaser shall pay the Supplier any monies due the Supplier.

30. Limitation of

30.1 Except in cases of criminal negligence or willful misconduct, and

Liability

in the case of infringement pursuant to Clause 7,

- (a) the Supplier shall not be liable to the Purchaser, whether in contract, tort, or otherwise, for any indirect or consequential loss or damage, loss of use, loss of production, or loss of profits or interest costs, provided that this exclusion shall not apply to any obligation of the Supplier to pay liquidated damages to the Purchaser and
- (b) the aggregate liability of the Supplier to the Purchaser, whether under the Contract, in tort or otherwise, shall not exceed the total Contract Price, provided that this limitation shall not apply to the cost of repairing or replacing defective equipment.

31. Governing Language

- 31.1 The Contract shall be written in the language **specified in the SCC**. Subject to GCC Clause 31, the version of the Contract written in the specified language shall govern its interpretation. All correspondence and other documents pertaining to the Contract that are exchanged by the parties shall be written in the same language.

32. Applicable Law

- 32.1 The Contract shall be interpreted in accordance with the laws of the Purchaser's country, unless otherwise **specified in the SCC**.

33. Notices

- 33.1 Any notice given by one party to the other pursuant to this Contract shall be sent to the other party in writing to the other party's address **specified in the SCC**.
- 33.2 A notice shall be effective when delivered or on the notice's effective date, whichever is later.

34. Taxes and Duties

- 34.1 A Supplier supplying Goods from abroad shall be entirely responsible for all taxes, stamp, duties, license fees, and other such levies imposed outside the Purchaser's country.

35. Good Faith

- 35.1 Both Purchaser and Supplier undertake to act in good faith with respect to each other's rights under this contract and to adopt all reasonable measures to ensure the realization of the objectives of this contract.

SECTION IV. SPECIAL CONDITIONS OF CONTRACT

SPECIAL CONDITIONS OF CONTRACT

The following Special Conditions of Contract shall supplement the General Conditions of Contract. Whenever there is a conflict, the provisions herein shall prevail over those in the General Conditions of Contract. The corresponding clause number of the GCC is indicated in parentheses.

1. Definitions (GCC Clause 1)

GCC 1.1 (a)	Duration of the contract will be from the date of contract signing up to 36 months . The contract may be further extended subject to the availability of fund and satisfactory performance of the supplier.
GCC 1.1 (f)	The end user is: SC as per Annex-B
GCC 1.1 (i)	The Purchaser is: icddr,b
GCC 1.1 (j)	The Purchaser's country is: Bangladesh
GCC 1.1 (n)	SCs located in approximately 66 locations under 23 districts (list of sites/location attached as Annex-B)
GCC 1.1 (o)	The Supplier is: [Name of Supplier]

3. Country of Origin (GCC Clause 3)

GCC 3.1	There are no Special Conditions of Contract applicable to GCC Clause 3 except Israel.
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4. Standards (GCC Clause 4)

GCC 4	Condoms supplied under this contract must meet Product technical Specifications as outlined in Section VII of this bid document and must comply with WHO/UNFPA Specification 2010 as outlined in Annex A .
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5. Certification of Goods in accordance with Laws of the Purchaser's Country (GCC Clause 6)

GCC 6.1	Product Registration Certification from the Directorate General of Drugs Administration, Bangladesh shall be obtained. In case the goods have not been registered before the bid submission, the successful bidder shall submit the NOC from the relevant authority (Directorate of Drug Administration) before the delivery of the goods.
GCC 6.2	The Effective Date of the Contract is the date the Contract Form is signed by the successful bidder and the Purchaser.
GCC 6.3	The time period shall be 30 days.

8. Performance Security (GCC Clause 8)

GCC 8.1	The Performance Security shall be 3% of the Total Contract Amount
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9. Inspections and Tests (GCC Clause 9)

GCC 9.1	In addition to Special Conditions of Contract applicable to GCC Clause 9.1, the following tests and inspection requirements are to be fulfilled: <ul style="list-style-type: none"> (a) All compliance testing and requirements will be as per Product Technical Specifications as outlined in Section VII Table 4 and WHO/UNFPA specifications 2010 from WHO accredited testing laboratory. (b) In regular case, the costs of conducting the quality control testing shall be borne by the Purchaser. But the cost of the subsequent testing due to rejection of condoms shall be borne by the Supplier. The rejection of condoms could be due to raw materials problems, manufacturing defects, QC problem / failures, bad storage condition,
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	<p>damage due to poor transportation and warehouse management</p> <p>(c) The successful bidder shall furnish the Test certificate (Certificate of Analysis) of each manufacturing lot to the Purchaser.</p>
10. Packing (GCC Clause 10)	
GCC 10.2	Additional requirements are indicated in the Section VII, Technical Specifications, and Annex A: WHO condom specifications, 2010.
11. Delivery and Documents (GCC Clause 11)	
GCC 11.1 & 11.3	<ul style="list-style-type: none"> The purchaser will initiate Purchase Order (PO) in favour of the successful supplier based on the programme requirement or at mutually agreed cycle. icddr,b will do the monitoring as and when required including necessary approval in design, packaging, plan, etc. (Ref. Section VII. Technical Specifications, Clause 3.0, 4.0, 7.0 and 8.0). The purchaser will share distribution plan of condoms with the successful supplier after receipt of "Accepted" QC report from the independent QC lab. icddr,b reserves the right to oversee the storage, distribution and quality assurance related issues at both the supplier and receivers' end, and provide technical advice if needed or perceived by icddr,b based on which the supplier will be accountable to act. Condom shall be delivered to the identified SCs (Annex-B) as per the agreed schedule. Upon delivery of the Goods, the Supplier shall submit the following document to the Purchaser: <ul style="list-style-type: none"> One copy of delivery note (Challan) duly sealed and signed by the SCs as mentioned in GCC1.1 (n) showing the final destination along with Goods' description, quantity as stated in the Contract. Copy of purchase order Invoice, mentioning the quantity, unit price, and the total value of the shipment delivered. Shipping documents, comprises of commercial invoice, packing list with information of batch no, date of manufacturing and expiry of the products, Bill of lading, country of origin certificate and any other documents deemed necessary and relevant.
12. Insurance (GCC Clause 12)	
GCC 12.1	For the Supplier, the liability of the Goods will be limited up to delivery of the goods to the SC points detailed by Purchaser while ensuring proper storage of Condoms in its own warehouses before delivery to purchasers as per "Standard Guidelines for Proper Storage of Health Commodities".(Annex-C)
14. Incidental Services (GCC Clause 14)	
GCC 14.1	<p>Incidental services to be provided are:</p> <p>The Supplier shall provide all necessary licenses and permissions for use of the Goods in the Purchaser's country that may be required for the Goods. The cost shall be deemed included in the Contract Price.</p>
15. Warranty (GCC Clause 15)	
GCC 15.4	The period of replacement of defective goods is: 06 (six) weeks
16. Payment (GCC Clause 16)	

GCC 16.1 16.3 & 16.4	Payment for Goods and Services supplied shall be made in USD through wire transfer within thirty (30) days upon delivery of condoms to the SCs and submission of invoice along with acceptance of quality and quantity of condoms certified by SCs and icddr,b.
17. Prices (GCC Clause 17)	
GCC 17.1	Prices shall be fixed for the duration of the Contract that is up to 36 months from the date of the contract signing. However, in case of increase of demand beyond the percentage mentioned at the Bid Data Sheet against ITT Clause 38.1, the price will be revised through amicable discussion between the purchaser and the supplier. Global market trend, inflation of the purchaser's country as declared by its Central Bank shall be taken into consideration for price review. In case of fixation of price for extended period of contract, same procedure will be followed.
18. Change Orders (GCC Clause 18)	
GCC 18	There is no Special Conditions of Contract applicable to GCC Clause 18. But the place of delivery may vary based on project requirements.
20. Renewal of Contract (GCC Clause 20)	
GCC 20	Duration of Renewal will be subject to GCC Clause 1.1a and GCC Clause 17.1.
23. Liquidated Damages (GCC Clause 23)	
GCC 23.1	0.5% (One half percent) of undelivered goods per week subject to a maximum of 10% (ten percent) of the Contract price
29. Settlement of Disputes (GCC Clause 29)	
GCC 29.2.2	In the case of a dispute between the Purchaser and a Supplier which is a national of the Purchaser's country as of local agent/distributor, the dispute shall be referred to adjudication or arbitration in accordance with the laws of Bangladesh.
31. Governing Language (GCC Clause 31)	
GCC 31.1	The governing language shall be English .
32. Applicable Law (GCC Clause 32)	
GCC 32.1	The Contract shall be interpreted in accordance with the laws of Bangladesh.
33. Notices (GCC Clause 33)	
GCC 33.1	<p>[Purchaser's address] icddr,b 68, Shaheed Tajuddin Ahmed Sarani Mohakhali, Dhaka-1212</p> <p>[Supplier's address for notice purposes will be inserted at the time of contract signing]</p>

SECTION V. BIDS AND CONTRACT FORMS

Notes to Bidders on the Preparation of Sample Forms

The Purchaser has prepared the forms in this section of the Bidding Documents to suit the specific requirements of the procurement. In its bid, the Bidder **MUST** use these forms (or forms that present in the same sequence substantially the same information). If the Bidder has a question regarding the meaning or appropriateness of the contents or format of the forms and/or the instructions contained in them, these questions should be brought to the Purchaser's attention as soon as possible during the bid clarification process, by addressing them to the Purchaser in writing pursuant to ITT Clause 10.

The Purchaser has provided explanatory text and instructions to help the Bidder prepare the forms accurately and completely. The instructions that appear directly on the forms themselves are indicated by use of typographical aides such as italicized text within square brackets.

In preparing its bid, the Bidder **MUST** ensure all such information is provided and that the typographical aides are removed.

BIDS AND CONTRACT FORMS

1. Bid Form
2. Price Schedule for Goods Offered from Abroad (To be Imported)
3. Bid Security Form
4. Form of Contract Agreement
5. Performance Security /Bank Guarantee
6. Manufacturer's Authorization Form
7. Proforma for Performance Statement
8. Specifications Submission and Compliance Sheet

1. Bid Form

Date: *[insert: date of bid]*

ITB No: icddr,b/SCM/OTM/2024/404

Supply & Distribution of Male Latex Condom

To:

.....

.....

Bangladesh

Dear Sir:

Having examined the Bidding Documents, including Addenda Nos *[insert numbers]*, the receipt of which is hereby acknowledged, we, the undersigned, offer to supply and deliver the Goods under the above-named Contract Package in full conformity with the said Bidding Documents for the sum of:

[insert: amount of currency in words] *[insert: amount of currency in figures]*

(hereinafter called "the Total Bid Price") or such other sums as may be determined in accordance with the terms and conditions of the Contract. The above amounts are in accordance with the Price Schedules attached herewith and are made part of this bid.

We undertake, if our bid is accepted, to deliver the Goods in accordance with the delivery schedule specified in the Schedule of Requirements.

If our bid is accepted, we undertake to provide a performance security in the form, in the amounts, and within the times specified in the Bidding Documents.

We agree to abide by this bid, for the Bid Validity Period specified in Clause 17.1 of the Bid Data Sheet and it shall remain binding upon us and may be accepted by you at any time before the expiration of that period.

Until the formal final Contract is prepared and executed between us, this bid, together with your written acceptance of the bid and your notification of award, shall constitute a binding Contract between us. We understand that you are not bound to accept the lowest or any bid you may receive.

Commissions or gratuities, if any, paid or to be paid by us to agents relating to this bid, and to contract execution if we are awarded the Contract, are listed below:

Name and Address of Agent	Amount and Currency	Purpose of Commission or Gratuity
_____	_____	_____
_____	_____	_____
_____	_____	_____

(if none, state "none")

We certify/confirm that we comply with the eligibility requirements as per ITT clause 4 and section III of the bidding documents.

Dated this [insert: **number**] day of [insert: **month**], [insert: **year**].

Signed: _____

Date: _____

In the capacity of [insert: **title or position**]

Duly authorized to sign this bid for and on behalf of [insert: **name of Bidder**]

2. Price Schedule for Goods Offered from Abroad (to be imported)

Name of the Bidder _____

Page of _____

ITB No : icddr,b/SCM/OTM/2024/404

Date 14 March 2024

Description: Supply & distribution of Male Latex Condom

1	2	3	4	5	6	7	8	9	10
Product	UOM	Quantity Offered	Cost Component (in %)	Unit Prices in USD (DDP)	Total Price (3X5) USD	Local Agent's Commission as a % of unit Price	H S Code	Name of Manufacturer	Country of Origin
Male Latex Condom (condom supply)	Each		Latex Cost						
			Other Chemical Cost						
			Production Cost (Electricity, Furnace oil, HSD Oil, Water Charges, Salaries etc.)						
			Strip Cost (Foil, Silicone oil, Primary packing, Wastage, Rejection etc.)						
			Packing Cost (Carton, box, other packaging materials)						
			Freight Charges						
Condom Distribution	Each		C&F Cost for Custom clearance						
			Export Country Logistics Cost (storage +distribution +transportation)						

Note:(i)For column 5, pursuant to ITT 33.1, in the case of discrepancy between unit price and total price, the unit price shall prevail.
(ii) DDP: "Delivered Duty Paid"

Total Bid Price:
In figures:
In words:

3. Bid Security Form

Date: *[insert: date of bid]*

ITB No: : icddr,b/SCM/OTM/2024/404.

Supply & Distribution of Male Latex Condom

To:

WHEREAS *[insert: **name of Bidder**]* (hereinafter called "the Bidder") has submitted its bid dated *[insert: **date of bid**]* for the performance of the above-named Contract (hereinafter called "the Bid")

KNOW ALL PERSONS by these present that WE *[insert: **name of bank**]* of *[insert: **address of bank**]* (hereinafter called "the Bank") are bound unto _____ (hereinafter called "the Purchaser") in the sum of: *[insert: **amount**]*, for which payment well and truly to be made to the said Purchaser, the Bank binds itself, its successors and assigns by these presents.

Sealed with the Common Seal of the said Bank this *[insert: **number**]* day of *[insert: **month**]*, *[insert: **year**]*.

THE CONDITIONS of this obligation are the following:

1. If, after the bid submission deadline, the Bidder
 - (a) withdraws its bid during the period of bid validity specified by the Bidder in the Bid Form, or
 - (b) does not accept the Purchaser's corrections of arithmetic errors in accordance with the Instructions to Bidders; or
2. If the Bidder, having been notified of the acceptance of its bid by the Purchaser during the period of bid validity
 - (a) fails or refuses to sign the Contract Agreement when required; or
 - (b) fails or refuses to issue the performance security in accordance with the Instructions to Bidders.

We undertake to pay to the Purchaser up to the above amount upon receipt of its first written demand, without the Purchaser having to substantiate its demand, provided that in its demand the Purchaser will note that the amount claimed by it is due it, owing to the occurrence of any one of the two above-named CONDITIONS, and specifying the occurred condition or conditions.

This guarantee will remain in full force up to and including *[insert: **the date that is 28 days after the period of bid validity**]*, and any demand in respect thereof must reach the Bank not later than the above date.

For and on behalf of the Bank

Signed: _

Date: _____

in the capacity of: *[insert: **title or other appropriate designation**]*

Common Seal of the Bank

4. Form of Contract Agreement

THIS CONTRACT AGREEMENT is made on the [insert: **number**] day of [insert: **month**], [insert: **year**].

BETWEEN

(1) _____,
(hereinafter called "the Purchaser")

(2) [insert: **name of Supplier**], a corporation incorporated under the laws of [insert: **country of Supplier**] and having its principal place of business at [insert: **address of Supplier**] (hereinafter called "the Supplier").

WHEREAS the Purchaser invited bids for certain goods and ancillary services, viz., supply and distribution of male latex condoms as stated in the schedule of requirements and has accepted a bid by the Supplier for the supply of those goods and services in the sum of [insert: **contract price in words and figures**] (hereinafter called "the Contract Price") under the following terms and conditions:

- a. Supplier shall ensure the timely supply of the goods to the designated locations as per purchaser's requirement.
- b. Supplier shall ensure the proper documentation in the Goods Receiving Procedures prescribed by the purchaser.
- c. The Supplier will be required to submit invoices in triplicate for the goods delivered along with signed challan. Payment will be made using an account payee cheque but only after thorough examination of the invoices and challans. Bills will not be processed and accepted without all the recipients' signed delivery challans.
- d. icddr,b will review and analyze the Certificate of Analysis (COA) submitted by the Supplier after production. If no response comes within 7 days, it will be considered as accepted. If any dispute arises, the test will be conducted any third country Lab and cost of testing will be borne by purchaser if the test result conforms by manufacturer test and vice versa.
- e. The decision of icddr,b will be final in case of any dispute arises between Supplier, and the icddr,b regarding this Bid and performance of the contract thereof.
- f. Supplier will be fully liable for all the risks for carrying goods from warehouse to warehouse. To cover such risks supplier shall be required to take 100% insurance coverage.
- g. In case of theft/breakdown of the hired truck, the supplier must make timely alternative arrangement for the services at his own cost. In case of failure to make an alternative arrangement, the supplier shall forego transportation charges and penalty will be imposed at a rate double the amount of the transportation charges or as decided by icddr,b. This will be recovered from the security deposit and outstanding bill if any. However, penalty will not be imposed if normal operation of vehicle cannot be made due to civil commotion, and such other situation beyond the control of the owner/contractor.

NOW THIS AGREEMENT WITNESSETH AS FOLLOWS:

1. In this Agreement words and expressions shall have the same meanings as are respectively assigned to them in the Conditions of Contract referred to.
2. The following documents shall constitute the Contract between the Purchaser and the Supplier, and each shall be read and construed as an integral part of the Contract:
 - (a) The Signed Contract Agreement
 - (b) The Purchaser's Notification of Award
 - (c) The Bid and appendices to the Bid
 - (d) Special Conditions of Contract
 - (e) General Conditions of Contract
 - (f) Technical Specifications
 - (g) Schedule of Requirement (including Drop in Centers and Implementation Schedule)
 - (h) The Supplier's bid and original Price Schedules
 - (i) *[Add here: **any other documents stated at SCC**]*
3. In consideration of the payments to be made by the Purchaser to the Supplier as hereinafter mentioned, the Supplier hereby covenants with the Purchaser to provide the Goods and Services and to remedy defects therein in conformity in all respects with the provisions of the Contract.
4. The Purchaser hereby covenants to pay the Supplier in consideration of the provision of the Goods and Services and the remedying of defects therein, the Contract Price or such other sum as may become payable under the provisions of the Contract at the times and in the manner prescribed by the Contract.

For and on behalf of the Purchaser:

Signed:

in the capacity of *[insert: **title or other appropriate designation]***
date:

in the presence of _____

For and on behalf of the Supplier

Signed:

in the capacity of *[insert: **title or other appropriate designation]***
date:

in the presence of _____

5. Performance Security Bank Guarantee

Date: [*insert: date of bid*]

Supply & Distribution of Male Latex Condom

To:

Dear Sir or Madam,

We refer to the Contract Agreement ("the Contract") signed on [*insert: **date***] between you and [*insert: **name of Supplier***] ("the Supplier") concerning the supply and delivery of [*insert: **a brief description of the Goods***] in accordance with the authority of your Notification of Award to the supplier dated (insert: *date*). Furthermore, We (name of Bank) understand that, according to your conditions, Contracts must be supported by a performance guarantee.

By this letter we, the undersigned, [*insert: **name of bank***], a bank (or company) organized under the laws of [*insert: **country of bank***] and having its registered/principal office at [*insert: **address of bank***], (hereinafter, "the Bank") do hereby jointly and severally with the Supplier irrevocably guarantee payment owed to you by the Supplier, pursuant to the Contract, up to the sum of [*insert: **amount in numbers and words***]. This guarantee shall be reduced or expire as provided for by GCC Sub-Clause 8.4.

We undertake to make payment under this Letter of Guarantee upon receipt by us of your first written demand signed by your duly authorized officer declaring the Supplier to be in default under the Contract and without cavil or argument any sum or sums within the above-named limits, without your need to prove or show grounds or reasons for your demand and without the right of the Supplier to dispute or question such demand. Our liability under this Letter of Guarantee shall be to pay to you whichever is the lesser of the sum so requested or the amount then guaranteed under this Letter in respect of any demand duly made under this Letter prior to expiry of this Letter of Guarantee, without being entitled to inquire whether or not this payment is lawfully demanded.

This Letter of Guarantee shall be valid from the date of issue until the date of expiration of the guarantee, as governed by the Contract. Except for the documents herein specified, no other documents or other action shall be required, notwithstanding any applicable law or regulation. Our liability under this Letter of Guarantee shall become null and void immediately upon its expiry, whether it is returned or not, and no claim may be made under this Letter after such expiry or after the aggregate of the sums paid by us to you shall equal the sums guaranteed under this Letter, whichever is the earlier. All notices to be given under this Letter shall be given by registered (airmail) post to the addressee at the address herein set out or as otherwise advised by and between the parties hereto.

We hereby agree that any part of the Contract may be amended, renewed, extended, modified, compromised, released, or discharged by mutual agreement between you and the Supplier, and this security may be exchanged or surrendered without in any way impairing or affecting our liabilities hereunder without notice to us and without the necessity for any additional endorsement, consent, or guarantee by us, provided, however, that the sum guaranteed shall not be increased or decreased.

No action, event, or condition that by any applicable law should operate to discharge us from liability hereunder shall have any effect, and we hereby waive any right we may have to apply such law, so that in all respects our liability hereunder shall be irrevocable and, except as stated herein, unconditional in all respects.

For and on behalf of the Bank

Signed: _____

Date: _____ Common Seal of the Bank.

6. Manufacturer's Authorization Form

(Manufacturer's or Producer's letterhead)

To:

WHEREAS [*insert: **name of the manufacturer***] (hereinafter, "we" or "us") who are established and reputable manufacturers or producers of [*insert: **name and/or description of the Goods requiring this authorization***] (hereinafter, "Goods") having production facilities at [*insert: **address of factory***] do hereby authorize [*insert: **name and address of Bidder***] (hereinafter, the "Bidder") to submit a bid, and subsequently negotiate and sign the Contract with you against ITB no.for supply of _____ [Name of the item].

We hereby extend our full guarantee and warranty in accordance with Clause 15 of the General Conditions of Contract with respect to the Goods offered by the above firm.

For and on behalf of the Manufacturer

Signed: _____

Date: _____

In the capacity of [*insert: **title, position, or other appropriate designation***] and duly authorize to sign this Authorization on behalf of [*insert: **name of manufacturer or producer***]

7. Pro-forma for performance statement

Order Placed By (Name and full address of the Purchaser)	Order No. and Date.	Description and Quantity of ordered of similar items	Value of Order	Date of Completion of Delivery		Remarks (indicating reasons for late delivery, if any)	Was the supply of similar forms satisfactory? (Attach a certificate from the Purchaser/Consignee)
				As per Contract	Actual		
MAJOR CONTRACTS ALREADY EXECUTED IN LAST 5 YEARS:							
CONTRACTS IN HAND (COMMITEMNT)							

Name of Bidder: -----

Signature and

Seal of the Bidder: -----

8. Specifications submission and compliance sheet**Name of Bidder** _____ **Page of** ____

ITB No : icddr,b/SCM/OTM/2024/404

Date 14 March 2024

Supply and distribution of Male Latex Condoms**Country of Origin** _____

Specification Description	Bidder's Comments/Compliance
1.0 General Requirement	
1.1 Material	
1.1.1 Constituent Material.	
1.1.2 Biocompatibility.	
1.1.3 Protein Level.	
1.1.4 Bio burden Level.	
1.1.5 Nitrosamines.	
1.1.6 Dusting powder.	
1.2 Shelf Life & Stability	
1.2.1 Shelf-life.	
1.2.2 Provisional shelf-life.	
1.2.3 Minimum Stability Requirements.	
1.3 Workmanship	
2.0 Performance Requirement	
2.1 Bursting Volume and Pressure	
2.2 Freedom from holes and visible defects	
2.3 Package seal integrity	

3.0 Design Requirements	
3.1 Shape and texture	
3.2 Integral bead	
3.3 Colour	
3.4 Odour, fragrance and flavor	
3.5 Testing	
3.6 Width	
3.7 Length	
3.8 Thickness	
3.9 Quantity of lubricant including powder	
3.10 Individual package materials and marking	
4.0 Packaging Requirements	
4.1 Inner boxes	
4.2 Exterior Shipping Cartons	
4.3 LOT Traceability	

Signature:

Name:

In the capacity of:

Duly authorized to sign the Tender for and on behalf of the Tenderer

**SECTION VI : SCHEDULE OF REQUIREMENTS
(MALE LATEX CONDOMS)**

Description	2024	2025	2026	Total	Remarks
Supply and distribution of Condoms [Brand: project approved name and foil design] up to the SC level	9,547,200 pcs	15,883,200 pcs	11,966,400 pcs	37,396,800 pcs	Distribution plan will be shared with the successful bidder based on programme requirement.

SPECIAL NOTES:

- * Goods would be transported in such a way that the integrity of the material of the goods is not negatively affected due to jerking or mishandling during loading and unloading of the goods and that storage conditions are maintained e.g. dry, well – ventilated covered carriers avoiding direct sunlight. Every precaution shall be taken to minimize the risk of theft and fraud. Quantities are tentative, and may change with the actual requirements.

SECTION VII. TECHNICAL SPECIFICATIONS

TECHNICAL SPECIFICATIONS OF MALE LATEX CONDOM

All condoms supplied under this invitation are to be in accordance with the WHO/UNFPA specifications, 2010 (Revised 2013), and, updated on 25 September 2020.

Specification Description	Requirement
1.0 General Requirement	
1.1 Material	<p>1.1.1 Constituent Material. The condoms shall be made of <i>natural rubber latex</i>. 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, sensitizing or otherwise harmful to the user of the condom under normal conditions of use.</p> <p>1.1.2 Biocompatibility. Biocompatibility assessments shall be conducted in accordance with <i>ISO 10993–1</i>. Specifically, tests shall be conducted for cytotoxicity according to <i>ISO 10993–5</i> and for irritation and sensitization according to <i>ISO 10993–10</i>. Manufacturers should choose accredited laboratories for these tests, and the results should be interpreted by an accredited toxicologist or other suitably qualified expert. Expert reports should be available for review.</p> <p>1.1.3 Protein Level. The recommended levels for soluble protein, as determined by the modified Lowry method, should be less than 200 µg/g. Manufacturers should take steps not to exceed this level and should monitor production periodically. Documentation recording protein levels should be available for review.</p> <p>1.1.4 Bio burden Level. Bioburden levels on packed condoms be maintained below 100 cfu and not be allowed to exceed 500 cfu. Bioburden levels be determined at least quarterly, by extracting the condoms with a neutralizing medium and determining the total viable aerobic count using appropriate test methods.</p> <p>1.1.5 Nitrosamines. Condoms must be adequately leached and washed, by using minimum amounts of accelerators and by choosing accelerators, such as zinc dibutyldithiocarbamate, that have a preferred safety profile.</p> <p>1.1.6 Dusting powder. A suitable dusting powder (e.g. cornstarch, magnesium and calcium carbonates) should be used to prevent the condoms from sticking together during manufacture and to allow them to unroll easily. Talc and lycopodium spores shall not be used. <i>Manufacturers should not use excess powder (maximum recommended is 50 mg per condom).</i></p>
1.2 Shelf Life & Stability	<p>1.2.1 Shelf-life. Condoms shall comply with the performance requirements of this <i>WHO/UNFPA Specification</i> throughout the stated shelf-life of the condom.</p> <p>The claimed shelf-life shall be not less than three years and not more than five years measured from the date of manufacture. The date of manufacture is the date that the condoms were dipped. Shelf-life shall be confirmed by real-time stability studies conducted at 28°C to 35°C according to the relevant clause in <i>ISO 4074</i>.</p>

	<p><i>Sampling, Conditioning, & Testing requirement.</i> In accordance with ISO 4074 and records to be provided.</p> <p>1.2.2 Provisional shelf-life. Pending the outcome of the real-time studies, manufacturers may estimate a provisional shelf-life using an accelerated ageing study.</p> <p><i>Sampling, Conditioning, & Testing requirement.</i> In accordance with ISO 4074 and records to be provided. If all three LOTS of condoms remain in compliance with the requirements for bursting properties, freedom from holes and package integrity specified in the relevant clauses of <i>ISO 4074</i> for a period of 120 days at $(50 \pm 2) ^\circ\text{C}$, a provisional shelf-life of three years may be assigned. If all three LOTS of condoms remain in compliance with the requirements for bursting properties, freedom from holes and package integrity specified in the relevant clauses of <i>ISO 4074</i> for a period of 180 days at $(50 \pm 2) ^\circ\text{C}$, a provisional shelf-life of five years may be assigned.</p> <p>1.2.3 Minimum Stability Requirements. Condoms shall comply with the minimum stability requirements defined in the relevant clause of <i>ISO 4074</i>. Condoms meeting these minimum stability requirements can be assumed to have a provisional shelf-life of two years.</p> <p><i>Sampling.</i> Three LOTS sampled in accordance with <i>ISO 2859-1</i> and Annex B of <i>ISO 4074</i>.</p> <p><i>Conditioning.</i> Incubate samples in their individual sealed containers according to the relevant annex of <i>ISO 4074</i>:</p> <ul style="list-style-type: none"> • One set for 168 ± 2 hours at $(70 \pm 2) ^\circ\text{C}$, and another set for (90 ± 1) days at $(50 \pm 2) ^\circ\text{C}$. • At the end of the incubation periods, withdraw the condoms and test for airburst properties, freedom from holes and package seal. • The incubation period at $(50 \pm 2) ^\circ\text{C}$ can be extended to 120 or 180 days in order to estimate a provisional shelf-life by accelerated ageing, in which case testing at 90 days is not necessary. <p><i>Testing Requirements.</i> All three LOTS of condoms shall remain in compliance with the requirements for bursting properties, freedom from holes and package integrity specified in the relevant clauses of <i>ISO 4074</i>.</p>
1.3 Workmanship	The condoms and their packaging shall be free of defects that affect their durability, detract from their appearance, or impair their serviceability.
2.0 Performance Requirement	
2.1 Bursting Volume and Pressure	<p><i>Sampling.</i> In accordance with <i>ISO 2859-1</i> General Inspection Level I. For prequalification testing at least Code Letter M as specified in Annex B of <i>ISO 4074</i> shall be used.</p> <p><i>Testing.</i> In accordance with test method in the relevant annex of <i>ISO 4074</i> and the relevant clause in <i>ISO 4074</i>.</p> <p><i>Requirement. Minimum bursting requirements as listed below:</i></p> <p>AQL 1.5%</p> <p>Volume: 16.0 dm³ for condoms with widths less than 50.0 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</p>

	measured in accordance with the relevant annex of <i>ISO 4074</i> at a point (75 ± 5) mm from the closed end.
2.2 Bursting Volume and Pressure after oven conditioning	<p><i>Sampling.</i> In accordance with <i>ISO 2859-1</i> General Inspection Level I. For prequalification testing at least Code Letter M as specified in Annex B of <i>ISO 4074</i> shall be used.</p> <p><i>Testing.</i> In accordance with test method in the relevant annex of <i>ISO 4074</i> and the relevant clause in <i>ISO 4074</i>.</p> <p><i>Requirement. Minimum bursting requirements as listed below:</i> AQL 1.5% Volume: 16.0 dm³ for condoms with widths less than 50.0 mm Pressure: 1.0 kPa (for all widths) 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.</p>
2.2 Freedom from holes and visible defects	<p><i>Sampling.</i> <i>ISO 2859-1</i> General Inspection Level I, but at least Code Letter M.</p> <p><i>Testing.</i> For prequalification testing at least Code Letter N as specified in Annex B of <i>ISO 4074</i> shall be used.</p> <p><i>Requirement.</i> In accordance with test method in the relevant annex of <i>ISO 4074</i>. Freedom from holes: AQL 0.25% Critical visible defects: AQL 0.4% Non-critical visible defects: AQL 2.5% <i>ISO 4074</i> describes a limited number of critical visible defects. WHO specifies an extended list of critical visible defects and a list of non-critical visible defects in Chapter 3, Clauses 2.1 and 2.2.</p>
2.3 Package seal integrity	<p><i>Sampling.</i> <i>ISO 2859-1</i> Inspection Level S-3.</p> <p><i>Testing.</i> In accordance with the package integrity test method in the relevant annex of <i>ISO 4074</i>.</p> <p><i>Requirement. AQL 2.5%</i></p>
3.0 Design Requirements	
3.1 Shape and texture	The surface of the condoms shall be smooth and non-textured. Condom shall have straight and parallel side without constrictions and with a visible shoulder leading to a reservoir poaches at the tip. Verification shall be made by visual inspection.
3.2 Integral bead	The open end of the condom shall have a rolled ring of latex, called an integral bead. Bead should be intact and integral with condom. Verification shall be made by visual inspection.
3.3 Colour	Condoms shall be translucent (clear) and without added coloring. Verification shall be made by visual inspection.
3.4 Odour, fragrance and flavor	The condoms shall be odorless to the degree approved by the purchaser at pre-qualification. The condoms shall not give off an unpleasant odor when the package is opened at any time after storage for the stated life of the product. The purchaser or the purchaser's agent will store 100 condoms at room temperature from each pre-qualified lot for use in resolving disputes. No fragrance or flavor is desired.
3.5 Testing	Odour testing should be included in ageing studies.
3.6 Width	<p><i>Sampling.</i> In accordance with <i>ISO 2859-1</i> Inspection Level S-2.</p> <p><i>Testing.</i> In accordance with the test method in the relevant annex of</p>

	<p><i>ISO 4074.</i> Requirement. 49 mm to 51 mm. AQL 1.0%</p>
3.7 Length	<p><i>Sampling.</i> In accordance with <i>ISO 2859–1</i> Inspection Level S-2. <i>Testing.</i> In accordance with the test method in the relevant annex of <i>ISO 4074.</i> Requirement. 165 mm to 180 mm. A minimum of 165 mm for condoms with widths less than 50.0 mm. A minimum of 180 mm for condoms with widths from 50.0 mm up to 55.5 mm. AQL 1.0% 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 (35 ± 15) mm from the open end, rounded to the nearest 0.5 mm.</p>
3.8 Thickness	<p><i>Sampling.</i> In accordance with <i>ISO 2859–1</i> Inspection Level S-2. <i>Testing.</i> In accordance with the test method in the relevant annex of <i>ISO 4074.</i> <i>Requirement.</i> 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. AQL 1.0% The mean single-wall thickness (calculated from the three individual measurements) for each condom shall be $0.065 + 0.015 \text{ mm} - 0.020 \text{ mm}$. Design</p>
3.9 Quantity of lubricant including powder	<p><i>Sampling.</i> In accordance with <i>ISO 2859–1</i> Inspection Level S-2. <i>Testing.</i> In accordance with the test method in the relevant annex of <i>ISO 4074.</i> <i>Requirement.</i> The condom shall be lubricated with a quantity of silicone fluid having a viscosity between 200 and 350 centistokes. <i>Other lubricants such as glycols and water-based lubricants may be used. Oil-based lubricants should NOT be used.</i> The quantity of lubricant, including powder, in the package should be (550 ± 150) mg. Required AQL 4.0%</p>
3.10 Individual package materials and marking	<p><i>Sampling.</i> In accordance with <i>ISO 2859</i> Inspection Level S-3. <i>Testing.</i> The sample of condom packages is visually inspected to verify the required aspects of package quality. <i>Requirement.</i> Individual packages shall be square and shall not distort the rolled condom. The package shall be hermetically sealed and shall protect the product from oxygen, ozone, water vapour, ultraviolet and visible light. Verified by visual inspection. Packages shall be constructed of a laminate, which includes a layer of suitable impermeable flexible aluminum foil of a minimum thickness of 8 micrometers and layers of plastic materials suitable for</p>

	<p>the mechanical protection of the metal foil and for printing and sealing. Verified by supplier's data or independent test</p> <p>The colour, print design and identification markings, including Pantone references and font sizes, shall be as specified by the purchaser and will be supplied at the time of contract agreement.</p> <p>Any lot numbers on packages must be printed at the time of packaging- not pre-printed. There shall be no evidence of leakage. Outside surface of the package shall be clean. There shall be no separation of the layers of the laminate. If the sealed packages are in strips, 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 can have a notch or serration to assist in opening.</p> <p><i>The individual package shall have the following markings:</i></p> <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 labeled expiry date; • Date in English and Bangla. • Manufacturing date: Month-and-year labeled manufacturing date; • Any other information as requested by icddr (i.e. brand name, logo etc.) <p>Required AQL 2.5%</p>
4.0 Packaging Requirements	
4.1 Inner boxes	<p>The inner boxes shall be constructed of cardboard. There shall be plastic coating on its inner surface to resist moisture. The boxes shall be of sufficient strength and rigidity to retain their shape through every stage of the distribution chain. The inner boxes will be marked in a legible manner to describe the contents and to facilitate identification in case of subsequent query. Inner boxes shall hold 144 (1 gross) individual condom packages in strips of three or four or as specified by the purchaser.</p> <p>The following information shall be included in the inner box marking:</p> <ul style="list-style-type: none"> • LOT identification number; • month and year of manufacture (including the words <i>Date of Manufacture, Month, Year</i>) in English and Bangla. The year will be written as a four-digit number and the month as a two-digit number; • month and year of expiry (including the words <i>Expiry Date, Month, Year</i>) in English and Bangla. The year will be written as a four-digit number and the month as a two-digit number; • manufacturer's name and registered address; • nominal width of the condom, expressed in millimeters; • number of condoms in box; • instructions for storage. <p>Note: All markings must be legible.</p> <p>Inner box markings can be changed by the purchaser in accordance with programme requirements during the contract execution.</p>
4.2 Exterior Shipping Cartons	<p>The inner boxes shall be packed into plastic or other waterproof lining bags, which will be placed in three-wall cartons made from weather-resistant corrugated fibre board with a bursting test</p>

	<p>strength of not less than 1900 kPa.</p> <p>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 center seams and extending over the ends by not less than 75 mm. The cartons shall be secured by plastic strapping at not less than two positions.</p> <p>The following information shall be labeled on the exterior shipping cartons on two opposing sides in bold letters, clearly visible, at least 50 mm high with waterproof ink:</p> <ul style="list-style-type: none"> • generic name and trade name • LOT identification number; • month and year of manufacture (including the words <i>Date of Manufacture, Month, Year</i>) in English and Bangla. 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 <i>Expiry Date, Month, Year</i>) in English and Bangla. The year shall be written as a four-digit number and the month as a two-digit number; • name and address of manufacturer; • consignee's address in full • nominal width; • number contained in the carton; • instructions for storage and handling. • gross weight of the carton (in kg.) <ul style="list-style-type: none"> • contract order number. • carton _____ of _____ and unique serial number <p>The exact printing shall be agreed prior to the award of contract.</p> <p>icddr, b will have the right to request the Supplier to imprint a logo on the packaging of the condom. Logo is to be provided by icddr,b.</p>
4.3 LOT Traceability	<p>To facilitate monitoring of lot quality during shipping and storage, all exterior shipping cartons for each discrete lot shall be assembled and shipped together.</p> <p>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.</p> <p>These efforts may include the use of very large lettering for LOT codes on the exterior shipping cartons; colour coding; using one pallet per LOT; physically linking all exterior shipping cartons from discrete LOTS; and issuing instructions to this effect to shippers and warehouse personnel.</p>

Table 1. Classification of Defects in Packaging and Marking of Packaging 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), incorrect location, sequences, 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.

Table 2: Critical Visible Defects for Male Latex Condom

AQL 0.4%	
Defect	Description
Pleat/crease	The film sticks to itself, and the pleat/crease cannot be removed by gentle stretching of the adjacent film.
Blister/bubble	An obvious circular or teardrop-shaped thin area with a well-defined border in the film. (Such defects may break under pressure.)
Coagulum (large)	Rubber particles with any dimension greater than 1 mm. These may cause the condom to fail in use.
Embedded and surface particles	Any particle with any dimension of 1 mm or greater. These may be dirt, hair, insects, powder granules, etc.
Bead defects	missing or severely distorted beads (as in ISO 4074).
Crack marks	Lines that penetrate the surface of the film, formed by shrinkage of the latex during drying. These do not include flow lines or marks from the mould.
Delamination	Areas where the individual layers of latex separate. (Condoms are formed by two or more dips in the liquid latex.)
Thin areas	Small areas of the condom (including the teat) that is visibly thin. These can show up as bulges with well-defined edges on the freedom-from-holes test. Condoms that look asymmetrical when filled with water are not necessarily in this category

Table 3: Non Critical Visible Defects for Male Latex Condom

AQL 2.5%	
Defect	Description
Embedded and surface particles (small)	Particles with dimensions less than 1 mm those are visible to the naked or corrected eye.
Faulty Bead (minor)	Uneven and partially distorted beads

Table 4. Summary of LOT-by-LOT Pre-shipment Compliance Testing and Requirements		
Sample according to Annex A in <i>ISO 4074</i> for "continuous LOTS" and <i>ISO 2859-1</i>		
Test	Sampling	Requirements
Performance Requirement		
Bursting volume (before and after oven conditioning)	Level G-I Minimum Code Letter M	Minimum volumes: 16.0 dm ³ for condoms with widths less than 50 mm AQL 1.5%
Bursting pressure (before and after oven conditioning)	Level G-I Minimum Code Letter M	Minimum pressure: 1.0 kPa AQL 1.5%
Freedom from holes	Level G-I Minimum Code Letter M	AQL 0.25%
Package integrity	Level S-3 Minimum Code Letter H	AQL 2.5%
Design Requirement		
Visible defects	Level G-I Minimum Code Letter N	Critical defects: AQL 0.4% Non-critical defects: AQL 2.5%
Shape and texture	Agreed between manufacturer and buyer	Visual inspection: Smooth & non-textured surface, straight and parallel side without constrictions and with a visible shoulder leading to a reservoir poaches at the tip
Integral bead	Agreed between manufacturer and buyer	Visual inspection: intact and integral with condom
Colour	Agreed between manufacturer and buyer	Visual inspection: translucent (clear) and without added coloring
Fragrance and flavouring	Agreed between manufacturer and buyer	Sensory inspection: no fragrance or flavour
Width	Level S-2	49 mm to 51 mm AQL 1.0%
Length	Level S-2	165 mm to 180 mm AQL 1.0%
Thickness	Level S-2	0.045–0.080 mm AQL 1.0%
Lubricant quantity (including powder)	Level S-2	Viscosity: 200–350 centistokes Qty: 400–700 mg/condom AQL 4.0%
Odour (if necessary)	Agreed between manufacturer and buyer	Sensory inspection
Packaging Requirement		
Inner box	Level S-3	Compliant with procurement specifications
Exterior shipping cartons	Level S-2	Compliant with procurement specifications
Individual package materials and marking	Level S-3	Compliant with procurement specifications AQL 2.5%

SECTION VIII: ANNEXURES

ANNEX-A: WHO SPECIFICATION OF MALE LATEX CONDOM

1. General Requirements

General Requirements are those properties of the condom that are not expected to change from LOT to LOT. Manufacturers are expected to include evidence that the products comply with the General Requirements in their Product Dossiers and Site Master File summaries.

1.1 Materials

Many of the materials used in latex formulations are irritating and sensitizing if used in excess. Manufacturers are required to demonstrate that their products are safe; using the appropriate sections of *ISO 10993 Biological Evaluation of Medical Devices*. In response to feedback from manufacturers, more details about the type of biological evaluations required and the specified parts of *ISO 10993* that apply to condoms are given in the *WHO/UNFPA Specification*. The safety assessment must include any dusting powder, colourant, lubricant and any other material that is added to the condom as well as any biocides added to the slurry, leach or washing solutions. A **dossier** containing the safety assessment, including expert reports interpreting the outcome of the studies, shall be made available to prospective purchasers. Summary reports must be included in the Product Dossier. Manufacturers may rely upon regulatory clearance from internationally recognized regulatory authorities to substantiate the safety of their products. Examples of acceptable approvals include a 510(k) premarket clearance to market the product from the U.S. Food and Drug Administration (USFDA) and approval for CE marking from a European Notified Body. When reliance upon such regulatory documentation is made, the manufacturer shall be required to supply all supporting documentation used in making the submission.

1.1.1 Allergic reaction

Two types of potential allergic reaction to latex condoms are possible. The first, more common potential risk is of a Type IV reaction. This type of reaction, also known as delayed hypersensitivity, most usually causes a skin rash (contact dermatitis). It is caused primarily by accelerator residues remaining in the condom. **Manufacturers are encouraged to minimize accelerator residues** by using the minimum amount of these chemicals in their formulations, effectively leaching and washing the condoms and choosing accelerators with a good safety profile such as zinc dibutyldithiocarbamate. The second type of allergic reaction is a Type I hypersensitivity to some of the naturally occurring water soluble proteins found in latex. This type of allergic reaction to condoms is extremely rare. One report cites the incidence of latex protein allergy amongst condom users as 0.08%. Type I allergic reactions tend to affect the respiratory system and can, in extreme circumstances, lead to anaphylaxis.

1.1.2 Protein levels

Manufacturers shall take every precaution through effective leaching and washing of the product to **maintain low levels of residual extractable proteins** and shall periodically determine the residual protein levels to confirm the effectiveness of the washing and leaching procedures. Feedback from manufacturers indicated that guidance on maximum permissible protein levels in condoms would be useful. Accordingly, a guideline **limit of not more than 200 µg of water-soluble protein**, as determined by the modified Lowry method, per gram of condom is recommended. There is no specific standard for determining the protein levels in

condoms; the methods described in **ISO 12243**, **EN 455-3** and **ASTM D5172** for determining the protein levels in medical gloves can be modified for condoms.

1.1.3 Nitrosamines

Chemicals known as nitrosamines can be formed in condoms in very small quantities, typically below 500 µg/kg by the interaction of accelerator residues in the condom with nitrogen oxides from the air. These chemicals are potentially carcinogenic. The levels of nitrosamines typically found in condoms constitute only a small proportion of normal nitrosamine exposure. Nevertheless, manufacturers should try to **minimize the amounts of nitrosamines** formed by using minimum amounts of accelerator, choosing accelerators, such as zinc dibutyldithiocarbamate, that have a preferred safety profile and ensuring that the condom is well leached.

1.1.4 Bioburden level

Condoms are not sterile products and, given their mode of use, there is no need for them to be sterile. Nevertheless, manufacturers are required to **minimize the risks of microbial contamination during manufacture and packaging**. In response to requests from the manufacturers, recommendations for the maximum recommended microbial bioburden on condoms prior to packaging are now included in the *WHO/UNFPA Specification*.

1.2 Shelf-life

Manufacturers are required to verify the shelf-life of their products using real-time stability studies. Critical to conducting these studies is the choice of a reference temperature appropriate to the expected storage conditions for the condoms in the destination countries. After long studies the reference temperature of the two most extreme climatic zones, Zone III (hot/dry) and Zone IV (hot/humid), was established as 30 °C. A tolerance of -2 °C has been allowed, based on conventional practice. The upper tolerance was increased to +5 °C to simplify temperature control requirements when conducting real-time stability studies in countries where ambient temperatures may periodically exceed 32 °C. WHO/UNFPA/ FHI Technical Review Committee Meeting, in July 2008, agreed to adopt the following requirements for shelf-life in the *WHO/UNFPA Specification*:

- Manufacturers shall confirm, using real-time studies at (30 +5 -2) °C, that the condoms comply with the performance requirements of the *WHO/ UNFPA Specification* throughout the stated shelf-life. Manufacturers shall stipulate a shelf life based on the outcome of stability studies and measured from the date of manufacture, which for the purposes of the *WHO/UNFPA Specification* is defined as the date of dipping. The stated **shelf-life shall be not less than three years and not more than five years** from the date of manufacture.
- Pending the outcome of real-time studies, manufacturers may claim a provisional shelf-life based on demonstrating compliance with the performance requirements of this *WHO/UNFPA Specification* on the basis of accelerated studies conducted at (50 ± 2) °C.
 - A provisional shelf-life of three years may be claimed after an ageing period of 120 days.
 - A provisional shelf-life of five years may be claimed after a period of 180 days.

It is emphasized that manufacturers are required to demonstrate that the condoms comply with all the performance requirements of the *WHO/UNFPA Specification* throughout the shelf-life of the product. This means that, as part of any stability study, changes in burst properties, freedom from holes and pack integrity will have to be monitored.

1.3 Minimum Stability Requirements

ISO/TC 157 has determined that all condoms shall meet minimum stability requirements before being placed on the market. This allows manufacturers and purchasers to assess the stability of a product relatively quickly. Additionally, it has been agreed that products meeting these requirements may be assigned a provisional shelf-life of two years. These requirements are specified in Clause 7.2 of *ISO 4074:2002* and will most probably be retained in the next edition of the standard.

The test for minimum stability includes accelerated conditioning regimens at (50 ± 2) °C for 90 days and (70 ± 2) °C for 7 days. The temperatures and times have been selected on the basis of practical experience with stability studies on condoms. Meeting these requirements does not imply that the condoms will have any specific shelf-life. In practice, it is anticipated that manufacturers will continue the study at (50 ± 2) °C for 120 and/or 180 days to estimate a provisional shelf-life for the product. The minimum stability test can be commenced as part of the prequalification stage of the procurement procedure and must be completed before any contract is confirmed.

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° C at maximum humidity for the stated shelf-life. These properties can only be determined directly through human use trials, but are verified by means of the laboratory test specified below. Allowance is made for a very small number of non-compliers, reflecting the state of the art of the manufacturing process as assessed by national and international standards authorities.

- 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 (production 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

The test methods and minimum burst volume and pressure requirements in this section are identical to those in *ISO 4074*. The pass/fail criterion is based on constraining the number of condoms bursting below the limits stated. ISO/TC 157 is currently considering introducing requirements for humidity control during burst testing. The proposed limits are $(55 \pm 15)\%$ relative humidity. If humidity control is adopted and incorporated into a future edition of *ISO 4074*, then by reference to this standard the same limits will apply to the test method specified in the *WHO/UNFPA Specification*.

2.2 Freedom from Holes and Visible Defects

A condom with a hole in it is clearly defective. The methods for testing for freedom from holes in the *WHO/UNFPA Specification* are identical to those in *ISO 4074*, as are the requirements. There are two alternative tests. The first is a visual test, in which the condom is filled with water and inspected for leakage. The second is a conductivity test, in which the condom is filled with a salt solution and immersed in a tank containing salt solution. An electrical voltage is applied across the film. If there is a hole in the condom, it is detected by a flow of current. Any holes detected by the electrical conductivity test are confirmed by the water test. Some modifications to the electrical test for freedom from holes are being considered by ISO/TC 157 based on recommendations from working group ISO/TC 157 WG 19. The proposed changes are intended to address possible issues with the sensitivity of the electrical test with certain types of condoms. The proposed changes include increasing the amount of electrolyte to 300 ml, filling the condoms with electrolyte before immersing them in the electrolyte bath, and applying the voltage between the condom and the electrolyte bath before the start of immersion. If these changes are adopted and incorporated into a future edition of *ISO 4074*, then by reference to this standard the same will also apply to the test method specified in the *WHO/UNFPA Specification*.

2.3 Package Seal Integrity

The purpose of the package is to protect the condom from mechanical damage, oxygen, ozone and light and to prevent lubricant from leaking. Exposure to oxygen, ozone and ultraviolet and visible light increases the risk of degradation of the condom. The test adopted is identical to that in *ISO 4074*. It involves putting the packs under water in a transparent container and then drawing a vacuum on the container. The packs are observed for signs of rising bubbles while under vacuum. The vacuum is then removed and the packs are opened for evidence of ingress of any water. The presence of rising bubbles while under vacuum or the ingress of water into the pack after removing the vacuum indicates a leaking pack.

3. Design Requirements

The recommended design features are specified, but they may be modified by the purchaser to suit local conditions and preferences. They are modified in the appropriate clause by mutual agreement among the purchaser, manufacturer and recipients. It is recommended that only well-established commercial designs be used. The differences in manufacturing costs for established designs are generally marginal, but it is expensive for a manufacturer to change a design or introduce a new one.

3.1 Shape and Texture

The conventional parallel-sided (cylindrical) condom shape has been in the WHO specification since it was first published. In the commercial sector a variety of other shapes are available. There are few studies on the relative acceptability and efficacy of condom shapes. Two of these studies indicate that approximately equal proportions of people preferred each of the variants covered in the trials. The design details of shaped condoms are specific to particular manufacturers who have the appropriate formers and testing mandrels. Selecting a particular non-parallel profile may thus reduce the range of possible suppliers. Textured condoms can be more difficult to manufacture. Depending upon the type and location of the texturing, it may be difficult to measure the thickness of textured condoms. Members of the Male Latex Condom Technical Review Committee agreed to make this version of the *WHO/UNFPA Specification* more flexible regarding the shape and texture of condoms that could be ordered for bulk procurement.

3.2 Integral Bead

The integral bead (or rim) is a ring of rubber at the open end of the condom.

3.3 Colour

Pigments may be added to the latex formulation. They need to be selected so that they are not harmful to the users as demonstrated by biocompatibility studies conducted according to *ISO 10993*. Some pigments may affect the physical properties of the rubber and increase the incidence of holes. Such pigments should not be used.

Appropriate methods of defining the colours shall be agreed upon between the manufacturer and purchaser. The use of Pantone colour charts may be useful. Strips that mix different coloured condoms are not recommended because they require the mixing of condoms from different LOTS. This complicates sampling for quality assurance as well as the tracing of defects.

3.4 Odour and Flavouring

Rubber products generally have some Odour. Inadequate washing of the product during manufacture and excess of some chemicals may cause a smell that is stronger than normal. Only subjective assessments of smell are practical at this stage. It is possible to mask the smell of rubber or provide a pleasant smell using some flavours or fragrances. It is, however, preferable to eliminate the Odour as far as possible by selection of formulation and processing conditions. Condoms often smell most strongly when the pack is first opened. Odours can disperse relatively quickly.

Flavouring can be used on condoms, especially if they may be used for oral sex. It is usual to add flavouring and fragrances to the lubricant. Fragrance and flavouring must be discussed and agreed on by the manufacturer and purchaser. They need to be selected so that they are not harmful to the users as demonstrated by biocompatibility studies conducted according to *ISO 10993*.

3.5 Width

Condom width is defined as the width when the condom is laid flat; it is half the circumference. The relative circumferences of the condom and penis determine how well the condom fits. Excessively large or small condoms relative to penis size appear to increase the risk of failure. It appears from the limited information available that three widths of condoms will meet the needs of most of the population. Condoms of a width of 49 mm are readily available from many manufacturers, and this is therefore the preferred size for a narrower condom. The standard width for condoms is usually 52 to 53 mm (WHO/ UNFPA specify 53 mm \pm 2 mm). There is no recognized size for larger condoms. Some manufacturers produce condoms of 56 mm width or more.

3.6 Length

Based on the information available in the literature and anecdotally, there is a weak correlation between mean penis circumference and mean penis length. As far as it is possible to ascertain from the limited data available at the country level, the narrower condoms should be shorter. Therefore, it is recommended that the minimum length of the condom depend upon the chosen width.

3.7 Thickness

The thickness range has been chosen to avoid both very thin and very thick condoms. The very thin products are likely to fail inflation requirements, while the

very thick ones appear to offer no added efficacy and are likely to be less acceptable to users. The normal thickness range for condoms is between 0.060- and 0.080-mm. Condoms thinner than 0.060 mm are normally classified as thin, and those thicker than 0.080 mm are normally classified as thick. The method of determining thickness follows *ISO 4074* and involves weighing a known area of the condom, then dividing by the density. Alternatively, the thickness may be determined using a micrometre with a foot diameter of (5 ± 2) mm and a foot pressure of (22 ± 4) kPa. It is expected that more details of the micrometre method will be included in the next edition of *ISO 4074*. The micrometre method can give different results than the weight method because of partial compression of the film during the micrometer test. Therefore, care should be taken in a contract to specify the referee method to be used. It is expected that the weight method will remain the preferred method in the next edition of *ISO 4074*. The Male Latex Condom Technical Review Committee agreed to retain measuring at the three specified locations along the condom length irrespective of the decision to be made by ISO/TC 157. *ISO 4074* currently specifies that the thickness shall be measured at three points along the length of the condom at 30 mm from the open end, at the midpoint and at 30 mm from the closed end.

3.8 Lubricant

Silicone fluid is the most commonly used lubricant for condoms and is therefore recommended. It is inert and has minimal effect on the properties of the latex film.

The quantity used has been selected to provide as high a level of lubrication as practical without creating package sealing problems in the factory. Other lubricants, especially glycols and water-based lubricants, can be used. If the lubricant used is water-based, preservatives may be needed to prevent microbial growth.

Powders are added to condoms to facilitate manufacturing and allow them to unroll easily. Acceptable powders include starch and calcium carbonate. Talc and mica should not be used. Manufacturers may use other powders by agreement with the purchaser. In such cases the choice of powder may need to be justified. Some manufacturers add biocides to the powder slurry to prevent bacterial growth. The choice of biocide and the amount used require careful consideration to achieve an acceptable level of bacterial control without increasing the risk of irritation or sensitization to end users and manufacturing personnel. A full risk assessment is required to justify the use of any biocide. Lubricant quantity is measured by weighing the condom and pack before and after washing and drying. The difference between these values is taken as the quantity of lubricant and powder added.

3.9 Spermicidal additives

Spermicidal additives to the lubricant have been used in some commercial products. Recent summaries of research findings suggest that these spermicides (predominantly nonoxynol-9) have significant irritant effects, and, overall, their use is not recommended.

3.10 Addition of medicinal substances to condom lubricants

In the commercial sector there is increasing availability of condoms containing medicinal substances. Many manufacturers incorporate the medicinal substance into a viscous gel or paste to localize it within the closed end of the condom. This is done to ensure that only the male partner is exposed to the active ingredients. If a medicinal substance is added to a condom, it is recommended that it is not added directly to the lubricant, as both partners will then be exposed to it. The most common example of a medicinal substance added to a condom is a local anesthetic such as benzocaine. Condoms containing medicinal substances are subject to local

regulatory requirements for medicines, and there may be legal issues with their distribution. **The inclusion of such products in bulk procurement programme is therefore not recommended in this *WHO/UNFPA Specification*.** It is suggested that individual bulk procurement agencies should consider all the issues before procuring this type of condom. Household products that should not be used with condoms:

- Baby oil
- Burn ointments
- Cooking oil
- Dairy butter
- Fish oil
- Haemorrhoid ointment
- Insect repellent
- Mineral oils
- Palm oil
- Petroleum jelly
- Rubbing alcohol
- Suntan oil

4. Packaging Requirement

Aluminum foil laminates are the most commonly used packaging material. It is important that the packaging protect the condom from oxygen, ozone and ultraviolet and visible light; be easy to open; and not leak lubricant. There are requirements for labeling individual packs to provide the minimum essential information for the end user. The labeling also helps to track the storage, supply and distribution of the condoms and can be used to locate LOTS if there are ever any questions about the quality of the product. In addition, it is a requirement of *ISO 4074* to include essential information for the condom user, which includes instructions for use, advice on disposal of the product after use, a statement that the condom is for single use only and the number of the international standard, *ISO 4074*. The Male Latex Condom Technical Review Committee recommended that, in addition, the *WHO/UNFPA Specification* include a requirement for a statement about the effectiveness of the condom.

ANNEX-B: LIST OF SCs (Tentative Distribution Sites)

Ser	District (# of SC established)	Location of SC
1	Dhaka Metropolitan (9)	Dhamrai, Uttara, Jatrabari, Darussalam, Badda, Demra, Lalbag, Uttara, Shyampur
2	Gazipur (5)	Gazipur Sadar, Polly Biddut, Tongi, Maona, Kaliganj
3	Narayanganj (4)	Narayanganj Sadar, Rupgonj, Vulta, Shonargaon
4	Mymensingh (2)	Mymensingh Sadar, Iswargonj,
5	Kishoregonj (2)	Bhairab, Kishoreganj Sadar,
6	Sylhet Metropolitan (2)	Sylhet Sadar, Jaflong
7	Moulavibazar (3)	Moulavibazar Sadar, Sreemangal, Shayestaganj
8	Chittagong Metropolitan (4)	Halishahar, Muradpur, Sitakundu, Mireswarai,
9	Noakhali (2)	Noakhali Sadar, Begumganj,
10	B.Barua (3)	B. Barua Sadar, Ashuganj, Akahaura
11	Narshingdi (3)	Narshingdi Sadar, Pachdona, Baroicha
12	Munshiganj (2)	Munshiganj Sadar, Sirajdikhan
13	Cox'sbazar (2)	Cox's Bazar Sadar, Chokoria
14	Comilla (3)	Comilla Sadar, Companyganj, Titash
15	Chandpur (2)	Chandpur Sadar, Matlab
16	Tangail (3)	Tangail Sadar, Ghatail, Gorai
17	Faridpur (2)	Faridpur Sadar, Vanga
18	Rajshahi (2)	Rajshahi Sadar, Arani
19	Bogra (3)	Bogra Sadar, Sherpur, Adamdighi
20	Dinajpur (2)	Dinajpur Sadar, Hili
21	Khulna Metropolitan (2)	Khulna Sadar, Khalishpur
22	Satkhira (2)	Satkhira Sadar, Shyamnagar
23	Barisal Metropolitan (2)	Barisal Sadar, Babuganj

ANNEX-C: STANDARD GUIDELINES FOR CONDOM STORAGE

Condom factories prequalified by UNFPA will have provided evidence to verify the claimed shelf-life of the product. The shelf-life is determined by a real-time study, conducted at a specific temperature ($30 \pm 5-2^\circ\text{C}$), because this is the mean kinetic temperature of the most extreme climate in climatic zones III and IV. Research has demonstrated that properly packaged good-quality condoms stored at average temperatures in tropical climates do not deteriorate during storage. More information about the rationale for choosing $30 \pm 5-2^\circ\text{C}$ as the storage temperature for stability studies is given in the Technical Basis Paper in Annex I. Since the shelf-life of the condoms will have been determined at $30 \pm 5-2^\circ\text{C}$, air-conditioned storage is not necessary, but it would be an advantage in hot climates if available. In hot climates it is important that condoms are stored in a well-ventilated environment away from direct sunlight and other sources of heat in order to minimize the exposure of the condoms to high temperatures. Similar precautions should be taken during transportation and delivery. Condoms stored outdoors in shipping containers are particularly vulnerable, as the temperatures inside containers can be substantially above ambient temperatures, resulting in faster deterioration. Storage time in containers should be minimized. The condoms are sealed in individual foil packages, which are themselves packed in cardboard. The cardboard storage containers are vulnerable to moisture and should be stored in a dry storeroom away from walls and placed on pallets to protect against rising damp. Cartons should be stored at least 10 cm off the floor, 30 cm away from the walls and stacked no more than 2.4 metres high.

Condoms are fully protected by the individual foil package. However, cosmetic damage to the foil and damage to the outer packaging can make the product appear damaged and therefore less acceptable to the user. Contaminants of any sort (e.g. powders or liquids) should be avoided. Condoms should be left in their original cartons and inner boxes until needed for distribution. The cartons should be positioned so that the LOT number and expiry date are visible. The cartons should be identified and their locations recorded to ensure that specific LOTS can be located. LOTS should be released on a *first expiry—first out basis* (FEFO). Damaged or expired condoms should be kept separately and disposed of in accordance with local procedures for the disposal of damaged medical devices. For additional information in chart format on condom storage, refer to: http://deliver.jsi.com/dlvr_content/resources/allpubs/guidelines/GuidPropStor_Char.pdf. For detailed information on the in-country management of storage and distribution, refer to the UNFPA-published *Condom Programming for HIV Prevention—An Operations Manual for Programme Managers* and PATH's *Procurement Capacity Toolkit: Tools and Resources for Procurement of Reproductive Health Supplies*.

Reference: Chapter 8, Condom Storage, Section 3; Male Latex Condom: Specification, Prequalification and Guidelines for Procurement, 2010.

ANNEX D: DOCUMENTS CHECK LIST

Ser	Document Title	Submission Status	
		Yes	No
1	Copy of the bid document duly sealed and signed by the bidder including all addendums (if any)	Yes	No
2	Valid Tax Identification Number (TIN) or equivalent for foreign entity both for manufacturer and agent	Yes	No
3	Trade license or equivalent for both manufacturer and agent	Yes	No
4	VAT registration number/BIN/equivalent for both manufacturer and agent	Yes	No
5	Written power of attorney authorizing the signatory of the bid to commit the Bidder	Yes	No
6	The completed specifications submission and compliance Sheet as furnished in Section V of ITB	Yes	No
7	Country of origin declarations	Yes	No
8	WHO/UNFPA Pre-qualification certificate of the manufacturer for condom	Yes	No
9	Registration from Local Authority / DGDA for the condom or NOC	Yes	No
10	Five years manufacturing experience documents	Yes	No
11	Evidence for three years' experience in distribution of health product	Yes	No
12	Evidence of required annual installed production capacity	Yes	No
13	Evidence of required annual turnover	Yes	No
14	A list of current contracts in hand (commitment)	Yes	No
15	At least three (3) nos. performance certificate undertaken in last 5 years	Yes	No
16	Copy of license by the National Drug Regulatory Authority (NDRA) in the country of manufacture to supply the Goods	Yes	No
17	GMP certificate from the NDRA in the country of manufacture for condoms	Yes	No
18	Documentation and certification for on-site quality management procedure, quality control laboratory facilities and services and range of tests conducted	Yes	No
19	Copies of audited financial statements and/or certified Annual Report for the last three fiscal years	Yes	No
20	Proof of experience of packing, distribution and transportation of condoms under logistical and climatic conditions similar to the purchaser's country	Yes	No
21	Affidavit on financial Solvency for the agent and manufacturer	Yes	No
22	Authorization of Local Agent as a representative of manufacturer, if applicable	Yes	No
23	Details of the Storage facilities through in the purchaser's country including the address and storage condition	Yes	No
24	Proposed distribution plan of condoms (mode of transport, required delivery time, etc.)	Yes	No
25	Bid Form	Yes	No
26	Price Schedule	Yes	No
27	Manufacturer's Authorization Form, if applicable	Yes	No
28	Separate Bid Submission for Technical & Financial proposal (Bid Form + Price Schedule)	Yes	No
29	Bid Validity for 180 days, confirmed by the bidder	Yes	No

Please circle "Yes" or "No" as appropriate