REQUEST FOR PROPOSAL

FOR

SUPPLY AND DISTRIBUTION OF

MALE LATEX CONDOMS (INTERNATIONAL)

OPEN TENDER METHOD

Project Name: ‘Prioritized HIV Prevention and Treatment Services for Key Populations in Bangladesh’

RFP No. icddr,b/SCM/OTM/2021/12 Dated: 18th March 2021
Request for Proposal
RFP No. icddr,b/SCM/OTM/2021/12; Date: 18th March 2021
FOR SUPPLY AND DISTRIBUTION OF MALE LATEX CONDOMS
(INTERNATIONAL)

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 follow 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 through email supplychain@icddrb.org no later than 19 March 2021 and indicate whether or not a bid shall be submitted. If you are declining to bid please state the reasons for icddr,b to improve its effectiveness in future Invitations.

6. Online Pre-tender meeting will be held on 25th Mar 2021 at 3:00pm. Please send your participating request to the email: supplychain@icddrb.org, within 23rd March 2021 COB; mention ‘Participation request in Pre-bid Meeting for Supply and Distribution of Male Latex Condom’ in the email subject. You also can share your queries regarding bid document and other issues in the same email which we will discuss in the pre-bid session.

7. All documentation relating to the bid must be received by icddr,b no later than 8th April 2021 at 2.30PM Dhaka Local Time (GMT+6). Submission will be through email [supplychain@icddrb.org]. 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 may be rejected.** Bid opening session will not be conducted as public opening.

8. **No Bid/Tender Security is required for participating in this bidding process.**

9. 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.

10. Bid document will be available in the icddr,b website [https://www.icddrb.org/work-with-us/tender-notices] and the responses for the received query will be circulated via email to all pre-bid participants.

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,

Qayyum Khan Manhbulb,
Sr. Manager, Procurement icddr,b
SECTION I. INSTRUCTIONS TO BIDDERS (RFP)
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
SECTION I. INSTRUCTIONS TO BIDDERS (RFP)

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 RFP and 23.1 of the General Conditions of Contract.

4. Eligible Bidders

4.1 Except as provided in RFP 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 RFP 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 RFP 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 RFP 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:
SECTION I. INSTRUCTIONS TO BIDDERS (RFP)

(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 RFP 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 RFP Clause 11.

SECTION I. INSTRUCTIONS TO BIDDERS
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 as separate documents.**

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 RFP 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 RFP 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 RFP 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
10

SECTION I. INSTRUCTIONS TO BIDDERS (RFP)

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 RFP 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 RFP 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 RFP 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 RFP 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 RFP 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 RFP Clause 6, in the Price Schedule for Goods and Related Services furnished in Section V: Bid and Contract Forms.
SECTION I. INSTRUCTIONS TO BIDDERS (RFP)

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 dis-aggregation 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 Interterms 2010), 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).

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 RFP 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
**SECTION I. INSTRUCTIONS TO BIDDERS (RFP)**

more than three foreign currencies may be used or as mentioned in the **Bid Data Sheet**.

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<th>17. Validity Period of Bids</th>
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<tr>
<td><strong>17.1</strong> Bids shall remain valid for the period stipulated in the <strong>Bid Data Sheet</strong> after the date of bid submission specified in RFP Clause 22. <em>A bid valid for a shorter period shall be rejected by the Purchaser as non-responsive.</em></td>
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<td><strong>17.2</strong> In justified exceptional circumstances, prior to expiry of the original bid validity period, the Purchaser may request <strong>not later than ten (10) days</strong> 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.</td>
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<td><strong>17.3</strong> Bidders consenting in writing to the request made by the Purchaser under RFP 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.</td>
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<td><strong>17.4</strong> A Bidder may refuse the request without forfeiting its bid security and its offer will not be considered for evaluation. Except as provided in RFP 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.</td>
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<th>18. Bid Security</th>
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<td><strong>18.1</strong> If required, in the Bid Data Sheet, the Bidder shall furnish, as part of its bid, a bid security as specified in the <strong>Bid Data Sheet</strong>, or a Bid Securing Declaration. The amount of the Bid Security shall be as stipulated in the <strong>Bid Data Sheet</strong> in the currency of the Purchaser’s country or equivalent US$.</td>
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<tr>
<td><strong>18.2</strong> 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.</td>
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<td><strong>18.3</strong> 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.</td>
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<td><strong>18.4</strong> 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.</td>
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<td><strong>18.5</strong> 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.</td>
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<td><strong>18.6</strong> The bid securities of non-responsive Bidders will be returned immediately after the Evaluation Report has been approved by the Purchaser.</td>
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<td><strong>18.7</strong> Bid securities of the responsive Bidders shall be returned only after the successful Bidder has submitted the performance security and</td>
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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 RFP 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 RFP Sub-Clause 39.1; or
   ii) sign the contract as stated under RFP Sub-Clause 42.2; or
   iii) furnish the required performance security as stated under RFP Sub-Clause 40.1; or does not accept the correction of the Bid price following the correction of arithmetic errors as stated under RFP 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 signed copy of the bidding document through email including the addendums issued (if any).

20.2 The Bidder need not to prepare or submit any hardcopy document considering COVID-19 pandemic and other health issues.

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 document/file 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 separate.

b) Financial proposal must be password protected and password would be shared with only the designated person as per instruction of TDS.

22. Deadline for Submission of Bids

22.1 Bids must be received by the Purchaser at the specific email address specified in the Bid Data Sheet relating to RFP 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 RFP 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 RFP 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 email to supplychain@icddrb.org of any modifications to its bid, clearly identified as such, “BID MODIFICATION-REQUEST”

(b) Other provisions concerning the marking and dispatch of bid modifications shall be in accordance with RFP Sub-Clauses 21.2 and 21.3.

24.3 A Bidder wishing to withdraw its bid 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,
SECTION I. INSTRUCTIONS TO BIDDERS (RFP)

(b) bear the specific identification of the bidding process (Contract name), the RFP title and RFP 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 RFP 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 RFP Clause 17. Withdrawal of a bid during this interval may result in the forfeiture of the Bidder’s bid security, pursuant to RFP Sub-Clause 18.8.

E. OPENING AND EVALUATION OF BIDS

25. Bid Opening

25.1 The bidder will submit the bid in two separate document/file/folder as stated in RFP 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.

25.2 The Purchaser will prepare a bid opening statement at the end of the opening session, for its internal record.

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 RFP 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:

<table>
<thead>
<tr>
<th>Sl. No.</th>
<th>Required Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Principal/manufacturer confirmation as UNFPA prequalified</td>
</tr>
<tr>
<td>2</td>
<td>Authentication of Local Agent as a representative of manufacturer</td>
</tr>
<tr>
<td>3</td>
<td>Submission of tender document with duly signed by the bidder</td>
</tr>
<tr>
<td>4</td>
<td>Separate Bid Submission for Technical &amp; Financial proposal</td>
</tr>
<tr>
<td>5</td>
<td>Submission of Legal Documents for both manufacturer and the appointed distribution agent</td>
</tr>
<tr>
<td></td>
<td>1. Trade License</td>
</tr>
<tr>
<td></td>
<td>2. VAT Certificate</td>
</tr>
<tr>
<td></td>
<td>3. TIN Certificate</td>
</tr>
<tr>
<td>6</td>
<td>Country of origin confirmation</td>
</tr>
<tr>
<td>7</td>
<td>Affidavit on financial Solvency for the agent and the manufacturer</td>
</tr>
<tr>
<td>8</td>
<td>Power of Attorney to the agent</td>
</tr>
<tr>
<td>9</td>
<td>Bid Validity for 180 days, confirmed by the bidder</td>
</tr>
<tr>
<td>10</td>
<td>UNFPA Pre-qualification certificate</td>
</tr>
<tr>
<td>11</td>
<td>Five Years Manufacturing Experience documents</td>
</tr>
<tr>
<td>12</td>
<td>Three years’ Experience in distribution of health product</td>
</tr>
<tr>
<td>13</td>
<td>Proof of minimum Production Capacity (&gt;40m pcs) for manufacturer</td>
</tr>
<tr>
<td>14</td>
<td>Proof of minimum annual turnover (&gt;0.4MUS$) for manufacturer</td>
</tr>
</tbody>
</table>
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 RFP Clauses shall be verified, failing which the Bid shall be considered as non-responsive.

31.1 Only those Bids surviving 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. | Comply with Technical Specification | WHO2010 and ISO4074 Approval from Local Authority / DGDA |
| ii. | Quality Control Management | On-site Quality Management procedure, quality control laboratory facilities & range of tests conducted |
| iii. | Production Capacity Vs Current Commitment | Number of Contracts in Hand, Annual Production Capacity, Financial Capacity |
| iv. | Reputation and Past Performance History | Contract 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 WHO2010 guideline for storing of Condom |
| iii. | Agent’s Distribution Management | Existing Distribution channel/Distribution Plan, if awarded |

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

32.1 Arithmetical errors will be rectified as follows:

a) 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.

b) If there is a discrepancy between subtotals and the total price, the total price shall be corrected.

c) If there is a discrepancy between words and figures, the amount in words will prevail.

d) 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:

(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. Financial Evaluation of Bid

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 RFP 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 RFP 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 RFP 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 RFP 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 take action 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 RFP 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
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 Award

39.1 Prior to the expiration of the period of bid validity and within seven (7) working days of receipt of the Intention 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 Notification of Intent shall be accepted in writing by the successful Bidder within seven (7) working days from the date of issuance of NOI.

39.3 The notification of intent 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 RFP Clause 40, the Purchaser will promptly notify each unsuccessful Bidder, pursuant to RFP 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 notification of award 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 RFP 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.

41.2 If the Performance Security submitted under RFP Clause 40.1 is not found to be authentic, the Purchaser shall proceed to take measures against the Bidder in accordance with RFP Sub-clause 40.2.

42. Signing of Contract

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 RFP Clause 40 or to sign the Contract, as stated under RFP 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 underlined mentioned for the relevant RFP clauses.

A. GENERAL

RFP 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

RFP 1.2 The Grant number, RFP no. and name of the Tender are:

Grant no. BGD-H-ICDDRB-1403
RFP No. icddr,b/SCM/OTM/2021/12 dated 18 March 2021

Name of tender: Supply and Distribution of Male Latex Condoms.
Scope of tender: Supply and Distribution of 20 million pieces of Male Latex Condoms up to the DIC level as per icddr,b approved name and foil design.

RFP 2.1 Project Name: ‘Prioritized HIV Prevention and Treatment Services for Key Populations in Bangladesh’

RFP 5.1 Eligible source countries: All countries except the state of Israel

RFP 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

RFP 7.1 (a) Qualification criteria for the Bidders are:

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 40 million pieces;
4. Required annual turnover shall be at least US Dollar 400,000 in any one of the last three years; and

Note: If the bidder is a supplier, the requirements under RFP - 7.1(a) i shall be of the concerned manufacturer (s) and the requirement under RFP 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 the numbers 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;
Electronic mail address: supplychain@icddrb.org

**Online Pre-bid meeting will be held on 25th March 2021 at 3:00 PM (GMT+6).** Please confirm your participation through email (above mentioned) within 23th March 2021 (CoB). Meeting link will be shared with you accordingly.

icddr,b preferred meeting platform is Microsoft Teams.

### B. THE BIDDING DOCUMENTS

#### C. PREPARATION OF BIDS

| RFP 12.1 | The language of all correspondence and documents related to the bid is **English**. |
| RFP 13.1 | In addition to the documents stated in Paragraphs 13.1 (a) through (i), the following documents shall be included with the Bid: |
|          | (a) Documentary evidence for qualifying WHO/UNFPA prequalification scheme for supplier/manufacturer 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/manufacturer 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. |
| RFP 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. |
| RFP 15.2 (a) | Prices for Goods offered from abroad shall be quoted as: DDP. The Drop in Centers (DIC) shall be as per Annex- B: List of distribution sites. |
| RFP 15.2 (b) | 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:

(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.

RFP 15.5 Prices quoted by the Bidder shall be **fixed for entire contract period**.

RFP 16.1 (a) Bidder’s supplying goods from outside the purchaser’s country shall quote prices in USD and shall receive payment in USD.

RFP 17.1 The Bid validity period shall be 180 (one hundred Eighty) days after the deadline of bid submission, as specified in RFP Clause 22.

RFP 18.1 No Bid Security will be required for participating in the bidding process.

RFP 20.2 Required number of copies of the bid: One Each Signed copy of Technical and Financial Proposal through email.
D. SUBMISSION OF BIDS

RFP 21.1 (b)  icddr,b only accept online submission for this RFP. No hardcopy submission is required.

RFP 21.2 (b)  For **Tender submission purposes** only, the Purchaser’s address is:
Attention: Director, Supply Chain & Facilities Management
Address: icddr,b
68, Shaheed Tajuddin Ahmed Sarani,
Mohakhali, Dhaka-1212.
Email: supplychain@icddrb.org

RFP 22.1  The deadline for the submission of Tenders is:
**Time & Date: 8th Apr 2021; 2:30 PM (Dhaka Local time)**
Email Address: supplychain@icddrb.org

RFP 23.1  • The bidder must follow Two-Envelop system for proposal submission. Which means, your technical and financial proposal must be separate and will be two individual document.
• Financial Proposal must be password protected and can be shared only with 'Shuraiya Parvin Banu shuraiya@icddrb.org; after the submission period but within the submission date.
• An unprotected financial proposal might lead the bidder for disqualification.
• Proposals must be in pdf format.
• Failure to comply above submission guideline may leads to non-qualified submission.

RFP 24.1  No bid shall be modified subsequent to the deadline for submission of bids.

E. BID OPENING AND EVALUATION

RFP 25.1  Bid Opening will be ‘Non-Public’
RFP 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
RFP 31.4, RFP 35  The Purchaser may visit Manufacturer /Local Agent office before signing of Contract.

F. AWARD OF CONTRACT

RFP 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)
SECTION III. GENERAL CONDITIONS OF CONTRACT
GENERAL CONDITIONS OF CONTRACT

1. Definitions

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

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

All Goods and Services supplied under the Contract shall have their origin in the countries and territories eligible under the rules...
SECTION III. GENERAL CONDITIONS OF CONTRACT

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 Contact 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
SECTION III. GENERAL CONDITIONS OF CONTRACT

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 kilometers 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 prejudice 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 practicable 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
(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.

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 Liability

30.1 Except in cases of criminal negligence or willful misconduct, and 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 31st March 2024. 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: DIC 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) Drop in Centers (DIC) located in approximately 32 locations under 27 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.

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.

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

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:
     (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
### SECTION IV. SPECIAL CONDITIONS OF CONTRACT

<table>
<thead>
<tr>
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<th>defects, QC problem / failures, bad storage condition, damage due to poor transportation and warehouse management (c) The successful bidder shall furnish the Test certificate (Certificate of Analysis) of each manufacturing lot to the Purchaser.</th>
</tr>
</thead>
</table>

#### 10. Packing (GCC Clause 10)


#### 11. Delivery and Documents (GCC Clause 11)

GCC 11.1 & 11.3
- 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 DICs (Annex-B) as per the agreed schedule. Upon delivery of the Goods, the Supplier shall submit the following document to the Purchaser:
  - One copy of delivery note (Challan) duly sealed and signed by the DICs 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 DIC 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 Incidental services to be provided are: 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.

#### 15. Warranty (GCC Clause 15)

GCC 15.4 The period of replacement of defective goods is: 06 (six) weeks

#### 16. Payment (GCC Clause 16)
### SECTION IV. SPECIAL CONDITIONS OF CONTRACT

<table>
<thead>
<tr>
<th>GCC Clause</th>
<th>Description</th>
</tr>
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<tbody>
<tr>
<td>16.1 &amp; 16.3 &amp; 16.4</td>
<td>Payment for Goods and Services supplied shall be made in USD through wire transfer within thirty (30) days upon delivery of condoms to the DICs and submission of invoice along with acceptance of quality and quantity of condoms certified by DICs and icddr,b.</td>
</tr>
</tbody>
</table>

### 17. Prices (GCC Clause 17)

| GCC 17.1 | Prices shall be fixed for the duration of the Contract that is up to 31st March 2024. However, in case of increase of demand, 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 | Purchaser’s address icddr,b 68, Shaheed Tajuddin Ahmed Sarani Mohakhali, Dhaka-1212  
Supplier’s address for notice purposes will be inserted at the time of contract signing |
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 RFP 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
3. Form of Contract Agreement
5. Manufacturer’s Authorization Form
6. Proforma for Performance Statement
7. Specifications Submission and Compliance Sheet
1. Bid Form

Date: [insert: date of bid]
RFP No: icddr,b/SCM/OTM/2021/12
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:

<table>
<thead>
<tr>
<th>Name and Address of Agent</th>
<th>Amount and Currency</th>
<th>Purpose of Commission or Gratuity</th>
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<td>(if none, state “none”)</td>
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We certify/confirm that we comply with the eligibility requirements as per RFP 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

**Name of the Bidder**

**RFP No:** icddr,b/SCM/OTM/2021/12

**Date:** 18th March 2021

**Description:** Supply & distribution of Male Latex Condom

<table>
<thead>
<tr>
<th>Product</th>
<th>UOM</th>
<th>Quantity Offered</th>
<th>Cost Component (in %)</th>
<th>Unit Prices in USD (DDP)</th>
<th>Total Price (3X5) USD</th>
<th>Local Agent’s Commission as a % of unit Price</th>
<th>H S Code</th>
<th>Name of Manufacturer</th>
<th>Country of Origin</th>
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<tr>
<td>Male Latex Condom (condom supply)</td>
<td>Each</td>
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<td>Latex Cost</td>
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<td>Other Chemical Cost</td>
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<td>Production Cost (Electricity, Furnace oil, HSD Oil, Water Charges, Salaries Etc)</td>
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<td>Strip Cost (Foil, Silicone oil, Primary packing, Wastage, Rejection Etc)</td>
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<td>Packing Cost (Carton, box, other packaging materials)</td>
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<td>Freight Charges</td>
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<td>Condom Distribution</td>
<td>Each</td>
<td></td>
<td>C&amp;F Cost for Custom clearance</td>
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<td>Export Country Logistics Cost (storage+distribution+transportation)</td>
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</table>

Note:
(i) For column 5, pursuant to RFP 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. 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 ____________________________________________

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 you or 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.
5. 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 RFP 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 farm.

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]
6. **Pro-forma for performance statement**

<table>
<thead>
<tr>
<th>Order Placed By (Name and full address of the Purchaser)</th>
<th>Order No. and Date.</th>
<th>Description and Quantity of ordered similar items</th>
<th>Value of Order</th>
<th>Date of Completion of Delivery</th>
<th>Remarks (indicating reasons for late delivery, if any)</th>
<th>Was the supply of similar forms satisfactory? (Attach a certificate from the Purchaser/Consignee)</th>
</tr>
</thead>
<tbody>
<tr>
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</tbody>
</table>

**MAJOR CONTRACTS ALREADY EXECUTED IN LAST 5 YEARS:**

<table>
<thead>
<tr>
<th>Name of Bidder:</th>
<th>Signature and Seal of the Bidder:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tbody>
</table>
# Specifications submission and compliance sheet

Name of Bidder ___________________________  Page of ___

RFP No : icddr,b/SCM/OTM/2021/12
Date__________________________
Supply and distribution of Male Latex Condoms

Country of Origin__________________________

<table>
<thead>
<tr>
<th>Specification Description</th>
<th>Bidder’s Comments/Compliance</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1.0 General Requirement</strong></td>
<td></td>
</tr>
<tr>
<td><strong>1.1 Material</strong></td>
<td></td>
</tr>
<tr>
<td>1.1.1 Constituent Material.</td>
<td></td>
</tr>
<tr>
<td>1.1.2 Biocompatibility.</td>
<td></td>
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<tr>
<td>1.1.3 Protein Level.</td>
<td></td>
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<tr>
<td>1.1.4 Bio burden Level.</td>
<td></td>
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<tr>
<td>1.1.5 Nitrosamines.</td>
<td></td>
</tr>
<tr>
<td>1.1.6 Dusting powder.</td>
<td></td>
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<tr>
<td><strong>1.2 Shelf Life &amp; Stability</strong></td>
<td></td>
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<tr>
<td>1.2.1 Shelf-life.</td>
<td></td>
</tr>
<tr>
<td>1.2.2 Provisional shelf-life.</td>
<td></td>
</tr>
<tr>
<td>1.2.3 Minimum Stability Requirements.</td>
<td></td>
</tr>
<tr>
<td><strong>1.3 Workmanship</strong></td>
<td></td>
</tr>
<tr>
<td><strong>2.0 Performance Requirement</strong></td>
<td></td>
</tr>
<tr>
<td>2.1 Bursting Volume and Pressure</td>
<td></td>
</tr>
<tr>
<td>Specifications submission and compliance sheet</td>
<td></td>
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<tr>
<td>------------------------------------------------</td>
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</tbody>
</table>

| 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)*

<table>
<thead>
<tr>
<th>Description</th>
<th>2021</th>
<th>2022</th>
<th>2023</th>
<th>Total</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Supply and distribution of Condoms [Brand: project approved name and foil design] up to the DIC level</td>
<td>8,539,200 pcs</td>
<td>6,775,200 pcs</td>
<td>4,685,600 pcs</td>
<td>20,000,000 pcs</td>
<td>Distribution plan will be shared with the successful bidder based on programme requirement.</td>
</tr>
</tbody>
</table>

**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.
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.

<table>
<thead>
<tr>
<th>Specification Description</th>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1.0 General Requirement</strong></td>
<td><strong>1.1 Material</strong></td>
</tr>
<tr>
<td><strong>1.1.1 Constituent Material.</strong> The condoms shall be made of natural rubber latex. 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.</td>
<td></td>
</tr>
<tr>
<td><strong>1.1.2 Biocompatibility.</strong> Biocompatibility assessments shall be conducted in accordance with ISO 10993–1. Specifically, tests shall be conducted for cytotoxicity according to ISO 10993–5 and for irritation and sensitization according to ISO 10993–10. 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.</td>
<td></td>
</tr>
<tr>
<td><strong>1.1.3 Protein Level.</strong> 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.</td>
<td></td>
</tr>
<tr>
<td><strong>1.1.4 Bio burden Level.</strong> 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.</td>
<td></td>
</tr>
<tr>
<td><strong>1.1.5 Nitrosamines.</strong> Condoms must be adequately leached and washed, by using minimum amounts of accelerators and by choosing accelerators, such as zinc dibutylthiourea, that have a preferred safety profile.</td>
<td></td>
</tr>
<tr>
<td><strong>1.1.6 Dusting powder.</strong> 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. Manufacturers should not use excess powder (maximum recommended is 50 mg per condom).</td>
<td></td>
</tr>
<tr>
<td><strong>1.2 Shelf Life &amp; Stability</strong></td>
<td><strong>1.2.1 Shelf-life.</strong> Condoms shall comply with the performance requirements of this WHO/UNFPA Specification throughout the stated shelf-life of the condom. 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 ISO 4074.</td>
</tr>
</tbody>
</table>
### SECTION VII. TECHNICAL SPECIFICATIONS

**Sampling, Conditioning, & Testing requirement.** In accordance with ISO 4074 and records to be provided.

**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.

*Sampling, Conditioning, & Testing requirement.* 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 *ISO 4074* for a period of **120 days** at (50 ± 2) °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 *ISO 4074* for a period of **180 days** at (50 ± 2) °C, a **provisional shelf-life of five years may be assigned.**

**1.2.3 Minimum Stability Requirements.** Condoms shall comply with the minimum stability requirements defined in the relevant clause of *ISO 4074.* Condoms meeting these minimum stability requirements can be assumed to have a provisional shelf-life of **two years.**

*Sampling.* Three LOTS sampled in accordance with ISO 2859–1 and *Annex B* of *ISO 4074.*

*Conditioning.* Incubate samples in their individual sealed containers according to the relevant annex of *ISO 4074:*

- One set for 168 ± 2 hours at (70 ± 2) °C, and another set for (90 ± 1) days at (50 ± 2) °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 ± 2) °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.

**Testing Requirements.** 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 *ISO 4074.*

### 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

*Sampling.* In accordance with *ISO 2859–1 General Inspection Level I.* For prequalification testing at least Code Letter M as specified in *Annex B* of *ISO 4074* shall be used.

*Testing.* In accordance with test method in the relevant annex of *ISO 4074* and the relevant clause in *ISO 4074.*

**Requirement.** **Minimum bursting requirements as listed below:**

- **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 *ISO 4074* at a point (75 ± 5) mm from the closed end.
### 2.2 Bursting Volume and Pressure after oven conditioning

**Sampling.** In accordance with *ISO 2859–1* General Inspection Level I. For prequalification testing at least Code Letter M as specified in Annex B of *ISO 4074* shall be used.

**Testing.** In accordance with test method in the relevant annex of *ISO 4074* and the relevant clause in *ISO 4074*.

**Requirement.** Minimum bursting requirements as listed below:

- **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 *ISO 4074* at a point (75 ± 5) mm from the closed end.

### 2.2 Freedom from holes and visible defects

**Sampling.** *ISO 2859–1* General Inspection Level I, but at least Code Letter M.

**Testing.** For prequalification testing at least Code Letter N as specified in Annex B of *ISO 4074* shall be used.

**Requirement.** In accordance with test method in the relevant annex of *ISO 4074*.

- **Freedom from holes:** **AQL 0.25%**
- **Critical visible defects:** **AQL 0.4%**
- **Non-critical visible defects:** **AQL 2.5%**

*ISO 4074* 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.

### 2.3 Package seal integrity

**Sampling.** *ISO 2859–1* Inspection Level S-3.

**Testing.** In accordance with the package integrity test method in the relevant annex of *ISO 4074*.

**Requirement.** **AQL 2.5%**

### 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

**Sampling.** In accordance with *ISO 2859–1* Inspection Level S-2.

**Testing.** In accordance with the test method in the relevant annex of *ISO 4074*.

**Requirement.** 49 mm to 51 mm.
### 3.7 Length

**Sampling:** In accordance with *ISO 2859–1* Inspection Level S-2.

**Testing:** In accordance with the test method in the relevant annex of *ISO 4074*.

**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 *ISO 4074* at a point (35 ± 15) mm from the open end, rounded to the nearest 0.5 mm.

### 3.8 Thickness

**Sampling:** In accordance with *ISO 2859–1* Inspection Level S-2.

**Testing:** In accordance with the test method in the relevant annex of *ISO 4074*.

**Requirement:** 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 mm – 0.020 mm.

### 3.9 Quantity of lubricant including powder

**Sampling:** In accordance with *ISO 2859–1* Inspection Level S-2.

**Testing:** In accordance with the test method in the relevant annex of *ISO 4074*.

**Requirement:** The condom shall be lubricated with a quantity of silicone fluid having a viscosity between 200 and 350 centistokes. Other lubricants such as glycols and water-based lubricants may be used. *Oil-based lubricants should NOT be used.* The quantity of lubricant, including powder, in the package should be (550 ± 150) mg.

**Required AQL 4.0%**

### 3.10 Individual package materials and marking

**Sampling:** In accordance with *ISO 2859* Inspection Level S-3.

**Testing:** The sample of condom packages is visually inspected to verify the required aspects of package quality.

**Requirement:**
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 aluminium foil of a minimum thickness of 8 micrometres and layers of plastic materials suitable for the mechanical protection of the metal foil and for printing and sealing. Verified by supplier’s data or independent test.
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. 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.

The individual package shall have the following markings:

- 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 icddrb (i.e. brand name, logo etc.)

Required AQL 2.5%

4.0 Packaging Requirements

4.1 Inner boxes

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.

The following information shall be included in the inner box marking:

- LOT identification number;
- month and year of manufacture (including the words Date of Manufacture, Month, Year) 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 Expiry Date, Month, Year) 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.

Note: All markings must be legible.

Inner box markings can be changed by the purchaser in accordance with programme requirements during the contract execution.

4.2 Exterior Shipping Cartons

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 strength of not less than 1900 kPa.
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 centre 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.

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:

- generic name and trade name
- LOT identification number;
- month and year of manufacture (including the words Date of Manufacture, Month, Year) 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 Expiry Date, Month, Year) 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.)
- contract order number.

- carton__________of __________and unique serial number

The exact printing shall be agreed prior to the award of contract.

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.

### 4.3 LOT Traceability

To facilitate monitoring of lot quality during shipping and storage, all exterior shipping cartons for each discrete lot shall be assembled and shipped together. 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. 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.

<table>
<thead>
<tr>
<th>Table 1. Classification of Defects in Packaging and Marking of Packaging for Delivery</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Examine</strong></td>
</tr>
<tr>
<td><strong>Contents</strong></td>
</tr>
<tr>
<td><strong>Marking</strong></td>
</tr>
<tr>
<td><strong>Materials</strong></td>
</tr>
<tr>
<td>--------------</td>
</tr>
<tr>
<td><strong>Workmanship</strong></td>
</tr>
</tbody>
</table>
### Table 2: Critical Visible Defects for Male Latex Condom

<table>
<thead>
<tr>
<th>AQL 0.4%</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pleat/crease</td>
<td>The film sticks to itself, and the pleat/crease cannot be removed by gentle stretching of the adjacent film.</td>
</tr>
<tr>
<td>Blister/bubble</td>
<td>An obvious circular or teardrop-shaped thin area with a well-defined border in the film. (Such defects may break under pressure.)</td>
</tr>
<tr>
<td>Coagulum (large)</td>
<td>Rubber particles with any dimension greater than 1 mm. These may cause the condom to fail in use.</td>
</tr>
<tr>
<td>Embedded and surface particles</td>
<td>Any particle with any dimension of 1 mm or greater. These may be dirt, hair, insects, powder granules, etc.</td>
</tr>
<tr>
<td>Bead defects</td>
<td>missing or severely distorted beads (as in ISO 4074).</td>
</tr>
<tr>
<td>Crack marks</td>
<td>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.</td>
</tr>
<tr>
<td>Delamination</td>
<td>Areas where the individual layers of latex separate. (Condoms are formed by two or more dips in the liquid latex.)</td>
</tr>
<tr>
<td>Thin areas</td>
<td>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</td>
</tr>
</tbody>
</table>

### Table 3: Non Critical Visible Defects for Male Latex Condom

<table>
<thead>
<tr>
<th>AQL 2.5%</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Embedded and surface particles (small)</td>
<td>Particles with dimensions less than 1 mm those are visible to the naked or corrected eye.</td>
</tr>
<tr>
<td>Faulty Bead (minor)</td>
<td>Uneven and partially distorted beads</td>
</tr>
<tr>
<td>Test</td>
<td>Sampling</td>
</tr>
<tr>
<td>------</td>
<td>----------</td>
</tr>
<tr>
<td><strong>Performance Requirement</strong></td>
<td></td>
</tr>
<tr>
<td>Bursting volume (before and after oven conditioning)</td>
<td>Level G-I Minimum Code Letter M</td>
</tr>
<tr>
<td>Bursting pressure (before and after oven conditioning)</td>
<td>Level G-I Minimum Code Letter M</td>
</tr>
<tr>
<td>Freedom from holes</td>
<td>Level G-I Minimum Code Letter M</td>
</tr>
<tr>
<td>Package integrity</td>
<td>Level S-3 Minimum Code Letter H</td>
</tr>
</tbody>
</table>

| **Design Requirement** | | |
| Visible defects | Level G-I Minimum Code Letter N | Critical defects: **AQL 0.4%** <br> 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** <br> **AQL 1.0%** |
| Length | Level S-2 | **165 mm to 180 mm** <br> **AQL 1.0%** |
| Thickness | Level S-2 | **0.045–0.080 mm** <br> **AQL 1.0%** |
| Lubricant quantity (including powder) | Level S-2 | Viscosity: 200–350 centistokes <br> Qty: 400–700 mg/condom <br> **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 <br> **AQL 2.5%** |
SECTION VIII: ANNEXURES
ANNEX-A: THE 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 dibutylthiocarbamate. 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 tends 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 dibutylthiocarbamate, 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 prequalification 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 ± 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 ± 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 \((5 \pm 2)\) mm and a foot pressure of \((22 \pm 4)\) 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 anaesthetic 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.

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**ANNEX-B: LIST OF DICs (DISTRIBUTION SITES)**

<table>
<thead>
<tr>
<th>Ser</th>
<th>District (# of DIC established)</th>
<th>Location of DIC and Sub-DIC</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Dhaka Metropolitan (5)</td>
<td>Dhamrai, Uttara, Jatrabari, Darussalam, Badda</td>
</tr>
<tr>
<td>No.</td>
<td>District</td>
<td>Sub-District</td>
</tr>
<tr>
<td>-----</td>
<td>---------------------</td>
<td>--------------------</td>
</tr>
<tr>
<td>2</td>
<td>Gazipur (1)</td>
<td>Gazipur</td>
</tr>
<tr>
<td>3</td>
<td>Narayangonj (1)</td>
<td>Narayanganj Sadar</td>
</tr>
<tr>
<td>4</td>
<td>Mymensingh (1)</td>
<td>Mymensingh Sadar</td>
</tr>
<tr>
<td>5</td>
<td>Kishoregonj (1)</td>
<td>Bhairab</td>
</tr>
<tr>
<td>6</td>
<td>Jamalpur (1)</td>
<td>Jamalpur Sadar</td>
</tr>
<tr>
<td>7</td>
<td>Sylhet Metropolitan (1)</td>
<td>Sylhet Sadar</td>
</tr>
<tr>
<td>8</td>
<td>Sunamgonj (1)</td>
<td>Sunamganj Sadar</td>
</tr>
<tr>
<td>9</td>
<td>Moulvibazar (1)</td>
<td>Moulavibazar Sadar</td>
</tr>
<tr>
<td>10</td>
<td>Habiganj (1)</td>
<td>Habiganj Sadar</td>
</tr>
<tr>
<td>11</td>
<td>Chittagong Metropolitan (2)</td>
<td>Halishahar, Muradpur</td>
</tr>
<tr>
<td>12</td>
<td>Cox's Bazar (1)</td>
<td>Cox's Bazar Sadar</td>
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<td>13</td>
<td>Comilla (1)</td>
<td>Comilla Sadar</td>
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<tr>
<td>14</td>
<td>Tangail (1)</td>
<td>Tangail Sadar</td>
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<tr>
<td>15</td>
<td>Faridpur (1)</td>
<td>Faridpur Sadar</td>
</tr>
<tr>
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<td>Rajshahi (1)</td>
<td>Rajshahi Sadar</td>
</tr>
<tr>
<td>17</td>
<td>Chapai Nawabganj (1)</td>
<td>Chapai Sadar</td>
</tr>
<tr>
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<td>Sirajgonj (1)</td>
<td>Sirajganj Sadar</td>
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<tr>
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<td>Pabna (1)</td>
<td>Pabna Sadar</td>
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<td>Bogra Sadar</td>
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<tr>
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<td>Rangpur Metropolitan (1)</td>
<td>Rangpur Sadar</td>
</tr>
<tr>
<td>22</td>
<td>Dinajpur (1)</td>
<td>Dinajpur Sadar</td>
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<td>23</td>
<td>Khulna Metropolitan (1)</td>
<td>Khulna Sadar</td>
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<tr>
<td>24</td>
<td>Jessore (1)</td>
<td>Jessore Sadar</td>
</tr>
<tr>
<td>25</td>
<td>Satkhira (1)</td>
<td>Satkhira Sadar</td>
</tr>
<tr>
<td>26</td>
<td>Barisal Metropolitan (1)</td>
<td>Barisal Sadar</td>
</tr>
<tr>
<td>27</td>
<td>Patuakhali (1)</td>
<td>Patuakhali Sadar</td>
</tr>
</tbody>
</table>

**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 +5-2 °C), because this is the mean kinetic temperature of the most extreme climate in climatic zones III and IV. Research has

supply & distribution of male latex condom

icddrb supply chain
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 ±5-2 °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 ±5-2 °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-4: Minimum Document List for Technical Proposal

<table>
<thead>
<tr>
<th>SL. No.</th>
<th>Criteria</th>
<th>Reference clauses</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Principal/manufacturer information</td>
<td>RFP7.1(ii)(a), Section II</td>
</tr>
<tr>
<td>2</td>
<td>Local Agent information</td>
<td>RFP7.1(ii)(a), Section II</td>
</tr>
<tr>
<td>3</td>
<td>Submission of the tender document with duly signed</td>
<td>RFP13.1(a), section I</td>
</tr>
<tr>
<td>4</td>
<td>Separate Bid Submission for Technical &amp; Financial</td>
<td>RFP30.1(a), RFP Sub-clause 9.2, Section I</td>
</tr>
<tr>
<td>5</td>
<td>Submission of Legal Documents</td>
<td>RFP30.1(d), RFP Sub-clause 13.1(h), Section I</td>
</tr>
<tr>
<td></td>
<td>1. Trade License</td>
<td></td>
</tr>
<tr>
<td></td>
<td>2. VAT Certificate</td>
<td></td>
</tr>
<tr>
<td></td>
<td>3. TIN Certificate</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>Country of origin</td>
<td>RFP30.1(b), RFP Sub-clause 13.1(i), Section I</td>
</tr>
<tr>
<td>7</td>
<td>Affidavit on financial Solvency</td>
<td>RFP30.1(e), RFP Sub-clause 13.1(g), Section I</td>
</tr>
<tr>
<td>8</td>
<td>Power of Attorney</td>
<td>RFP30.1(f), RFP Sub-clause 13.1(e), Section I</td>
</tr>
<tr>
<td>9</td>
<td>Bid Validity for 180 days</td>
<td>RFP30.1(g), RFP Sub-clause 13.1(d), RFP Sub-clause 17.1 in Section I &amp; II.</td>
</tr>
<tr>
<td>10</td>
<td>UNFPA Pre-qualification Certificate</td>
<td>RFP30.2(a) in Section I, RFP7.1(a) in Section II</td>
</tr>
<tr>
<td>11</td>
<td>Five Years Manufacturing Experience</td>
<td>RFP30.2(a) in Section I, RFP7.1(a) in Section II</td>
</tr>
<tr>
<td>12</td>
<td>Three years’ Experience in distribution</td>
<td>RFP30.2(a) in Section I, RFP7.1(a) in Section II</td>
</tr>
<tr>
<td>13</td>
<td>Minimum Production Capacity (&gt;40m pcs)</td>
<td>RFP30.2(a) in Section I, RFP7.1(a) in Section II</td>
</tr>
<tr>
<td>14</td>
<td>Minimum Annual Turnover (&gt;0.4MUS$)</td>
<td>RFP30.2(a) in Section I, RFP7.1(a) in Section II</td>
</tr>
<tr>
<td>15</td>
<td>Three years audit reports</td>
<td>RFP7.1(a) in Section II</td>
</tr>
</tbody>
</table>

Above mention lists are not exclusive. Bidders are requested to go through the RFP documents properly and submit all necessary documents and proof of evidence where required and asked.