

Reference No: JPC/2019-20

# **Standard Bidding Documents**

## **Joint Procurement of Contraceptives for Health & Population Welfare Departments including Merged Districts**

### **National Competitive Bidding (Condoms, IUCDs & Implants)**



**GOVERNMENT OF  
KHYBER PAKHTUNKHWA**

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**Part I**  
**Section I**

**Instruction to bidders**

## **Instructions to Bidders**

### **A. Introduction**

#### **1. Source of Funds**

- 1.1 The Procuring entities i.e DoH and PWD including Merged Districts has received/applied for loan/grant/federal/provincial/local government funds from the source(s) indicated in the bidding data in various currencies towards the cost of the project /schemes specified in the bidding data and it is intended that part of the proceeds of this loan/grant/funds/ will be applied to eligible payments under the contract for which these bidding documents are issued therein no JPC/IHP/2019-20
- 1.2 The funds referred to above in addition shall be “Public Fund” which according to 2 (l) of KPP Rules 2014 means ( i ) Provincial Consolidated Fund; ( ii) foreign assistance; ( iii) all moneys standing in the Public Account; and (iv) Funds of enterprises wholly or partly owned or managed or controlled by Government.
- 1.3 Payment by the Fund will be made only at the request of the Procuring agency and upon approval by the Government of Khyber Pakhtunkhwa., and in case of a project will be subject in all respect to the terms and conditions of the agreement. The Project Agreement prohibits a withdrawal from the allocated fund account for the purpose of any payment to persons or entities, or for any import of goods, if such payment or import, to the knowledge of the Federal Government/ Khyber Pakhtunkhwa Government, is prohibited by a decision of the United Nations Security Council taken under Chapter VII of the Charter of the United Nations. No party other than the Procuring agency shall derive any rights from the Project Agreement or have any claim to the allocated fund proceeds.

#### **2. Eligible Bidders**

- 2.1 This Invitation for Bids is open to all suppliers from eligible source as defined in the KPP Rules, 2014 and its Bidding Documents except as provided hereinafter.
- 2.2 Bidders should not be associated, or have been associated in the past, directly or indirectly, with a firm or any of its affiliates which have been engaged by the Procuring agency to provide consulting services for the preparation of the design, specifications, and other documents to be used for the procurement of the goods to be purchased under this Invitation for Bids.
- 2.3 Government-owned enterprises in the Province of Khyber Pakhtunkhwa may participate only if they are legally and financially autonomous, if they operate under commercial law, and if they are not a dependent agency of the Government of Khyber Pakhtunkhwa.

2.4 Bidders shall not be eligible to bid if they are under a declaration of ineligibility for corrupt and fraudulent practices issued by any government organization in accordance with the Section 44(1) KPP Rules 2014.

2.5 Firms of a country may be excluded from bidding if as a matter of law or official regulation, the Government of Pakistan prohibits commercial relations with that country;

### **3. Eligible Goods and Services**

3.1 All goods and related services to be supplied under the contract shall have their origin in eligible source countries of the world with whom the Islamic Republic of Pakistan has commercial relations and its Bidding Documents and all expenditures made under the contract will be limited to such goods and services.

3.2 For purposes of this clause, “origin” means the place where the goods are mined, grown, or produced, or the place from which the related services are supplied. Goods are produced when, through manufacturing, processing, or substantial and major assembly of components, a commercially-recognized 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 Bidder.

3.4 All goods of international manufacturers to be supplied must be WHO / UNFPA prequalified. Goods supplied by national manufacturers will be exempted from WHO / UNFPA prequalification and will follow specifications as registered in DRAP for items to be quoted in this bidding or **even if applied for the registration of the quoted item and shall provide valid proof of the same could be considered.** However, all batches/lots of locally manufactured contraceptives would be tested from the Central Drug Testing Laboratory, Karachi, and Drug Testing Laboratory concerned (if the testing facility is available) Pakistan at supplier’s expense, as per Drug Act standard sampling procedure. In case of any doubt, for quality assurance of locally manufactured contraceptives, the Procuring Agency reserves the right to get any of the supplied batches/lots tested (up to maximum number of 05 batches/lots from the whole consignment) from any WHO/UNFPA accredited lab on the risk and cost of the Supplier.

### **4. Cost of Bidding**

4.1 The Bidder shall bear all costs associated with the preparation and submission of its bid, and the Procuring agency named in the Bid Data Sheet, hereinafter referred to as “the Procuring agency,” will in no case be responsible or liable for those costs, regardless of the conduct or outcome of the bidding process.

- 5. Content of Bidding Documents**
- B. The Bidding Documents**
- 5.1 The bidding documents include:
- Instructions to Bidders (ITB)
  - Bid Data Sheet
  - General Conditions of Contract (GCC)
  - Special Conditions of Contract (SCC)
  - Schedule of Requirements
  - Technical Specifications
  - Bid Form and Price Schedules
  - Bid Security Form
  - Contract Form
  - Performance Security Form
  - Manufacturer's Authorization Form
- 5.2 The Bidder is expected to examine all instructions, forms, terms, and specifications in the bidding documents. Failure to furnish all information required by the bidding documents or to submit a bid not substantially responsive to the bidding documents in every respect will be at the Bidder's risk and may result in the rejection of its bid.
- 6. Clarification of Bidding Documents**
- 6.1 An interested Bidder requiring any clarification of the bidding documents may notify the Procuring agency in writing. The Bidding Procuring agency will respond in writing to any request for Documents clarification of the bidding documents which it receives no later than three working days prior to the deadline for the submission of bids prescribed in the Bid Data Sheet. Written copies of the Procuring agency's response (including an explanation of the query but without identifying the source of inquiry) will be sent to all interested bidders that have received the bidding documents.
- 7. Amendment of Bidding Documents**
- 7.1 At any time prior to the deadline for submission of bids, the Procuring agency, for any reason, whether at its own initiative or in response to a clarification requested by an interested Bidder, may modify the bidding documents by amendment.
- 7.2 All interested bidders that have received the bidding documents will be notified of the amendment in writing, and will be binding on them.
- 7.3 In order to allow interested bidders reasonable time in which to take the amendment into account in preparing their bids, the Procuring agency, at its discretion, may extend the deadline for the submission of bids.

### **C. Preparation of Bids**

- 8. Language of Bid**
- 8.1 The bid prepared by the Bidder, as well as all correspondence and documents relating to the bid exchanged by the Bidder and the Procuring agency 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.
- 9. Documents**
- 9.1 The bid prepared by the Bidder shall comprise the following

<b>Comprising the Bid</b>	<p>components:</p> <ul style="list-style-type: none"> <li>a) a Bid Form and a Price Schedule completed in accordance with ITB Clauses 10, 11, and 12</li> <li>b) documentary evidence established in accordance with ITB Clause 13 that the Bidder is eligible to bid and is qualified to perform the contract if its bid is accepted;</li> <li>c) documentary evidence established in accordance with ITB Clause 14 that the goods and ancillary services to be supplied by the Bidder are eligible goods and services and conform to the bidding documents; and</li> <li>d) bid security furnished in accordance with ITB Clause 15.</li> </ul>
<b>10. Bid Form</b>	10.1 The Bidder shall complete the Bid Form and the appropriate 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.
<b>11. Bid Prices</b>	<p>11.1 The Bidder shall indicate on the appropriate Price Schedule the unit prices (where applicable) and total bid price of the goods it proposes to supply under the contract.</p> <p>11.2 Prices indicated on the Price Schedule shall be Delivered at Place (DAP). The price of other (incidental) services, if any, listed in the Bid Data Sheet will be entered separately.</p> <p>11.3 The Bidder's separation of price components in accordance with ITB Clause 11.2 above will be solely for the purpose of facilitating the comparison of bids by the Procuring agency and will not in any way limit the Procuring agency's right to contract on any of the terms offered.</p> <p>11.4 Prices quoted by the Bidder shall be fixed (unchanged) during the Bidder's performance of the contract and not subject to variation on any account, unless otherwise specified in the Bid Data Sheet. A bid submitted with an adjustable price quotation will be treated as nonresponsive and will be rejected, pursuant to ITB Clause 24. 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 adjustment would be treated as zero.</p>
<b>12. Bid Currencies</b>	12.1 Prices shall be quoted in Pak Rupees unless otherwise specified in the Bid Data Sheet.
<b>13. Documents Establishing Bidder's Eligibility and Qualification</b>	<p>13.1 Pursuant to ITB Clause 9, the Bidder shall furnish, as part of its bid, documents establishing the Bidder's eligibility to bid and its qualifications to perform the contract if its bid is accepted.</p> <p>13.2 The documentary evidence of the Bidder's eligibility to bid shall establish to the Procuring agency's satisfaction that the Bidder, at the time of submission of its bid, is from an eligible country as defined under ITB Clause 3.</p> <p>13.3 The documentary evidence of the Bidder's qualifications to perform the contract if its bid is accepted shall establish to the Procuring agency's satisfaction:</p> <ul style="list-style-type: none"> <li>a) that, in the case of a Bidder offering to supply goods under the</li> </ul>

contract which the Bidder did not manufacture or otherwise produce, the Bidder has been duly authorized by the goods' Manufacturer or producer to supply the goods in the Procuring agency's country;

- b) that the Bidder has the financial, technical, and production capability necessary to perform the contract;
- c) that, in the case of a Bidder not doing business within the Procuring agency's country, the Bidder is or will be (if awarded the contract) represented by an Agent in that country equipped, and able to carry out the Supplier's maintenance, repair, and spare parts-stocking obligations prescribed in the Conditions of Contract and/or Technical Specifications; and
- d) that the Bidder meets the qualification criteria listed in the Bid Data Sheet.

**14. Documents Establishing Goods' Eligibility and Conformity to Bidding Documents**

- 14.1 Pursuant to ITB Clause 9, the Bidder shall furnish, as part of its bid, documents establishing the eligibility and conformity to the bidding documents of all goods and services which the Bidder proposes to supply under the contract.
- 14.2 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 which shall be confirmed by a certificate of origin issued at the time of shipment.
- 14.3 The documentary evidence of conformity of the goods and services to the bidding documents may be in the form of literature, drawings, and data, and shall consist of:
  - a) a detailed description of the essential technical and performance characteristics of the goods;
  - b) a list giving full particulars, including available sources and current prices of spare parts, special tools, etc., necessary for the proper and continuing functioning of the goods for a period to be specified in the Bid Data Sheet, following commencement of the use of the goods by the Procuring agency; and
  - c) an item-by-item commentary on the Procuring agency'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.
- 14.4 For purposes of the commentary to be furnished pursuant to ITB Clause 14.3(c) above, the Bidder shall note that standards for workmanship, material, and equipment, as well as references to brand names or catalogue numbers designated by the Procuring agency in its Technical Specifications, are intended to be descriptive only and not restrictive. The Bidder may substitute alternative standards, brand names, and/or catalogue numbers in its bid, provided that it demonstrates to the Procuring agency's satisfaction that the substitutions ensure substantial equivalence to those designated in the Technical Specifications.



## **15. Bid Security**

- 15.1 Pursuant to ITB Clause 9, the Bidder shall furnish, as part of its bid, a bid security in the amount specified in the Bid Data Sheet.
- 15.2 The bid security is required to protect the Procuring agency against the risk of Bidder's conduct which would warrant the security's forfeiture, pursuant to ITB Clause 15.7.
- 15.3 The bid security under the framework agreement mode of procurement shall be in Pak. Rupees and shall be in one of the following forms:
- a) All those financial tools will be acceptable to the procuring entity which are allowed under the KPPRA Act and Rules 2014 prevailing rules and valid for thirty (30) days beyond the validity of the bid; or
- 15.4 Any bid not secured in accordance with ITB Clauses 15.1 and 15.3 will be rejected by the Procuring agency as non-responsive, pursuant to ITB Clause 24.
- 15.5 Unsuccessful bidders' bid security will be discharged or returned as promptly as possible but not later than thirty (30) days after the expiration of the period of bid validity prescribed by the Procuring agency pursuant to ITB Clause 16.
- 15.6 The successful Bidder's bid security will be discharged upon the Bidder signing the contract, pursuant to ITB Clause 32, and furnishing the performance security, pursuant to ITB Clause 33.
- 15.7 The bid security may be forfeited:
- a) if a Bidder withdraws its bid during the period of bid validity specified by the Bidder on the Bid Form; or
  - b) in the case of a successful Bidder, if the Bidder fails:
    - i. to sign the contract in accordance with ITB Clause 32;
    - or
    - ii. to furnish performance security in accordance with ITB Clause 33.

## **16. Period of Validity of Bids**

- 16.1 Bids shall remain valid for the period specified in the Bid Data Sheet after the date of bid opening prescribed by the Procuring agency, pursuant to ITB Clause 19. A bid valid for a shorter period shall be rejected by the Procuring agency as non-responsive.
- 16.2 In exceptional circumstances, the Procuring agency may solicit the Bidder's consent to an extension of the period of validity. The request and the responses thereto shall be made in writing. The bid security provided under ITB Clause 15 shall also be suitably extended. A Bidder may refuse the request without forfeiting its bid security. A Bidder granting the request will not be required nor permitted to modify its bid, except as provided in the bidding document.

## **17. Format and Signing of Bid**

- 17.1 The Bidder shall prepare an original and the number of copies of the bid indicated in the Bid Data Sheet, clearly marking each "ORIGINAL BID" and "COPY OF BID," as appropriate. In the event of any discrepancy between them, the original shall govern.

- 17.2 The original and the copy or copies of the bid shall be typed or written in indelible ink and shall be signed by the Bidder or a person or persons duly authorized to bind the Bidder to the contract. All pages of the bid, except for un-amended printed literature, shall be initialed by the person or persons signing the bid.
- 17.3 Any interlineations, erasures, or overwriting shall be valid only if they are initialed by the person or persons signing the bid.
- 17.4 The Bidder shall furnish information as described in the Form of Bid on commissions or gratuities, if any, paid or to be paid to agents relating to this Bid, and to contract execution if the Bidder is awarded the contract.

#### **D. Submission of Bids**

#### **18. Sealing and Marking of Bids**

- 18.1 The Bidder shall seal the original and each copy of the bid in separate envelopes, duly marking the envelopes as “ORIGINAL” and “COPY.” The envelopes shall then be sealed in an outer envelope.
- 18.2 The inner and outer envelopes shall:
- be addressed to the Procuring agency at the address given in the Bid Data Sheet; and
  - bear the Project name indicated in the Bid Data Sheet, the Invitation for Bids (IFB) title and number indicated in the Bid Data Sheet, and a statement: “DO NOT OPEN BEFORE,” to be completed with the time and the date specified in the Bid Data Sheet, pursuant to ITB Clause 2.2.
- 18.3 The inner envelopes shall also indicate the name and address of the Bidder to enable the bid to be returned unopened in case it is declared “late”.
- 18.4 If the outer envelope is not sealed and marked as required by ITB Clause 18.2, the Procuring agency will assume no responsibility for the bid’s misplacement or premature opening.

#### **19. Deadline for Submission of Bids**

- 19.1 Bids must be received by the Procuring agency at the address specified under ITB Clause 18.2 no later than the time and date specified in the Bid Data Sheet.
- 19.2 The Procuring agency may, at its discretion, extend this deadline for the submission of bids by amending the bidding documents in accordance with ITB Clause 7, in which case all rights and obligations of the Procuring agency and bidders previously subject to the deadline will thereafter be subject to the deadline as extended.

#### **20. Late Bids**

- 20.1 Any bid received by the Procuring agency after the deadline for submission of bids prescribed by the Procuring agency pursuant to ITB Clause 19 will be rejected and returned unopened to the Bidder.

#### **21. Modification And Withdrawal of Bids**

- 21.1 The Bidder may modify or withdraw its bid after the bid’s submission, provided that written notice of the modification, including substitution or withdrawal of the bids, is received by the Procuring agency prior to the deadline prescribed for submission of bids.
- 21.2 The Bidder’s modification or withdrawal notice shall be prepared,

sealed, marked, and dispatched in accordance with the provisions of ITB Clause 18 by a signed confirmation copy, postmarked not later than the deadline for submission of bids.

21.3 No bid may be modified after the deadline for submission of bids.

21.4 No bid may be withdrawn in the interval between the deadline for submission of bids and the expiration of the period of bid validity specified by the Bidder on the Bid Form. Withdrawal of a bid during this interval may result in the Bidder's forfeiture of its bid security, pursuant to the ITB Clause 15.7.

### **E. Opening and Evaluation of Bids**

#### **22. Opening of Bids by the Procuring agency**

22.1 The Procuring agency will open all bids in the presence of bidders' representatives who choose to attend, at the time, on the date, and at the place specified in the Bid Data Sheet. The bidders' representatives who are present shall sign a register evidencing their attendance.

22.2 The bidders' names, bid modifications or withdrawals, bid prices, discounts, and the presence or absence of requisite bid security and such other details as the Procuring agency, at its discretion, may consider appropriate, will be announced at the opening. No bid shall be rejected at bid opening, except for late bids, which shall be returned unopened to the Bidder pursuant to ITB Clause 20.

22.3 Bids (and modifications sent pursuant to ITB Clause 21.2) that are not opened and read out at bid opening shall not be considered further for evaluation, irrespective of the circumstances. Withdrawn bids will be returned unopened to the bidders.

22.4 The Procuring agency will prepare minutes of the bid opening.

#### **23. Clarification of Bids**

23.1 During evaluation of the bids, the Procuring agency may, at its discretion, ask the Bidder for a clarification of its bid. The Bids 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.

#### **24. Preliminary Examination**

24.1 The Procuring agency will examine the bids to determine whether they are complete, whether any computational errors have been made, whether required sureties have been furnished, whether the documents have been properly signed, and whether the bids are generally in order.

24.2 Arithmetical errors will be rectified on the following basis. 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 price shall prevail, and the total price shall be corrected. If the Supplier does not accept the correction of the errors, its bid will be rejected, and its bid security may be forfeited. If there is a discrepancy between words and figures, the amount in words will prevail.

24.3 The Procuring agency may waive any minor informality, nonconformity, or irregularity in a bid which does not constitute a material deviation, provided such waiver does not prejudice or affect the relative ranking of any Bidder.

24.4 Prior to the detailed evaluation, pursuant to ITB Clause 25 the Procuring agency will determine the substantial responsiveness of each bid to the

bidding documents. For purposes of these Clauses, a substantially responsive bid is one which conforms to all the terms and conditions of the bidding documents without material deviations. Deviations from, or objections or reservations to critical provisions, such as those concerning Bid Security (ITB Clause 15), Applicable Law (GCC Clause 30), and Taxes and Duties (GCC Clause 32), will be deemed to be a material deviation. The Procuring agency's determination of a bid's responsiveness is to be based on the contents of the bid itself without recourse to extrinsic evidence.

24.5 If a bid is not substantially responsive, it will be rejected by the Procuring agency and may not subsequently be made responsive by the Bidder by correction of the nonconformity.

## **25. Evaluation and Comparison of Bids**

25.1 The Procuring agency will evaluate and compare the bids which have been determined to be substantially responsive, pursuant to ITB Clause 24.

25.2 The Procuring agency's evaluation of a bid will be on Delivered at Place (DAP) price inclusive of prevailing duties and will exclude any allowance for price adjustment during the period of execution of the contract, if provided in the bid.

25.3 The Procuring agency's evaluation of a bid will take into account, in addition to the bid price quoted in accordance with ITB Clause 11.2, one or more of the following factors as specified in the Bid Data Sheet, and quantified in ITB Clause 25.4:

- a. incidental costs
- b. delivery schedule offered in the bid;
- c. deviations in payment schedule from that specified in the Special Conditions of Contract;
- d. the cost of components, mandatory spare parts, and service;
- e. the availability Procuring agency of spare parts and after-sales services for the equipment offered in the bid;
- f. the projected operating and maintenance costs during the life of the equipment; the performance and productivity of the equipment offered; and/or
- g. other specific criteria indicated in the Bid Data Sheet and/or
- h. in the Technical Specifications.

25.4 For factors retained in the Bid Data Sheet pursuant to ITB 25.3, one or more of the following quantification methods will be applied, as detailed in the Bid Data Sheet:

- a. Incidental costs provided by the bidder will be added by Procuring agency to the Delivered At Place (DAP) price at the final destination.
- b. Delivery schedule.
  - i. The Procuring agency requires that the goods under the Invitation for Bids shall be delivered at the time specified in the Schedule of Requirements which will be treated as the base, a delivery "adjustment" will be calculated for bids by applying a percentage, specified in the Bid Data Sheet, of the DAP price for each week of delay beyond the base, and this will be added to the bid price for evaluation. No

credit shall be given to early delivery.

or

- ii. The goods covered under this invitation are required to be delivered (shipped) within an acceptable range of weeks specified in the Schedule of Requirement. No credit will be given to earlier deliveries, and bids offering delivery beyond this range will be treated as non-responsive. Within this acceptable range, an adjustment per week, as specified in the Bid Data Sheet, will be added for evaluation to the bid price of bids offering deliveries later than the earliest delivery period specified in the Schedule of Requirements.

or

- iii. The goods covered under this invitation are required to be delivered in partial shipments, as specified in the Schedule of Requirements. Bids offering deliveries earlier or later than the specified deliveries will be adjusted in the evaluation by adding to the bid price a factor equal to a percentage, specified in the Bid Data Sheet, of DAP price per week of variation from the specified delivery schedule.

c. Deviation in payment schedule:

- i. Bidders shall state their bid price for the payment schedule outlined in the SCC. Bids will be evaluated on the basis of this base price. Bidders are, however, permitted to state an alternative payment schedule and indicate the reduction in bid price they wish to offer for such alternative payment schedule. The Procuring agency may consider the alternative payment schedule offered by the selected Bidder.

or

- ii. The SCC stipulates the payment schedule offered by the Procuring agency. If a bid deviates from the schedule and if such deviation is considered acceptable to the Procuring agency, the bid will be evaluated by calculating interest earned for any earlier payments involved in the terms outlined in the bid as compared with those stipulated in this invitation, at the rate per annum specified in the Bid Data Sheet.

d. Cost of spare parts.

- i. The list of items and quantities of major assemblies, components, and selected spare parts, likely to be required during the initial period of operation specified in the Bid Data Sheet, is annexed to the Technical Specifications. The total cost of these items, at the unit prices quoted in each bid, will be added to the bid price.

or

- ii. The Procuring agency will draw up a list of high-usage and high-value items of components and spare parts, along with estimated quantities of usage in the initial period of operation specified in the Bid Data Sheet. The total cost of these items and quantities will be computed from spare parts unit prices submitted by the

Bidder and added to the bid price.

or

- iii. The Procuring agency will estimate the cost of spare parts usage in the initial period of operation specified in the Bid Data Sheet, based on information furnished by each Bidder, as well as on past experience of the Procuring agency or other procuring agencies in similar situations. Such costs shall be added to the bid price for evaluation.

- e. Spare parts and after sales service facilities in the Procuring agency's country.

The cost to the Procuring agency of establishing the minimum service facilities and parts inventories, as outlined in the Bid Data Sheet or elsewhere in the bidding documents, if quoted separately, shall be added to the bid price.

- f. Operating and maintenance costs.

Since the operating and maintenance costs of the goods under procurement form a major part of the life cycle cost of the equipment, these costs will be evaluated in accordance with the criteria specified in the Bid Data Sheet or in the Technical Specifications.

- g. Performance and productivity of the equipment.

- i. Bidders shall state the guaranteed performance or efficiency in response to the Technical Specification. For each drop in the performance or efficiency below the norm of 100, an adjustment for an amount specified in the Bid Data Sheet will be added to the bid price, representing the capitalized cost of additional operating costs over the life of the plant, using the methodology specified in the Bid Data Sheet or in the Technical Specifications.

or

- ii. Goods offered shall have a minimum productivity specified under the relevant provision in the Technical Specifications to be considered responsive. Evaluation shall be based on the cost per unit of the actual productivity of goods offered in the bid, and adjustment will be added to the bid price using the methodology specified in the Bid Data Sheet or in the Technical Specifications.

- h. Specific additional criteria indicated in the Bid Data Sheet and/or in the Technical Specifications.

The relevant evaluation method shall be detailed in the Bid Data Sheet and/or in the Technical Specifications.

## **Alternative**

### **25.5 Merit Point System:**

The following merit point system for weighing evaluation factors can be applied if none of the evaluation methods listed in 25.4 above has been retained in the Bid Data Sheet. The number of points allocated to each factor shall be specified in the Bid Data Sheet.

[In the Bid Data Sheet, choose from the range of]

Evaluated price of the goods	60 to 90
Cost of common list spare parts	0 to 20
Technical features, and maintenance and operating costs	0 to 20
Availability of service and spare parts	0 to 20
Standardization	0 to 20
Total	100

The bid scoring the highest number of points will be deemed to be the lowest evaluated bid.

**26. Contacting the Procuring agency**

- 26.1 Subject to ITB Clause 23, no Bidder shall contact the Procuring agency on any matter relating to its bid, from the time of the bid opening to the time the contract is awarded. If the Bidder wishes to bring additional information to the notice of the Procuring agency, it should do so in writing.
- 26.2 Any effort by a Bidder to influence the Procuring agency in its decisions on bid evaluation, bid comparison, or contract award may result in the rejection of the Bidder's bid.

**F. Award of Contract**

**27. Post-qualification**

- 27.1 In the absence of prequalification, the Procuring agency will determine to its satisfaction whether the Bidder that is selected as having submitted the lowest evaluated responsive bid is qualified to perform the contract satisfactorily, in accordance with the criteria listed in ITB Clause 13.3.
- 27.2 The determination will take into account the Bidder's financial, technical, and production capabilities. It will be based upon an examination of the documentary evidence of the Bidder's qualifications submitted by the Bidder, pursuant to ITB Clause 13.3, as well as such other information as the Procuring agency deems necessary and appropriate.
- 27.3 An affirmative determination will be a prerequisite for award of the contract to the Bidder. A negative determination will result in rejection of the Bidder's bid, in which event the Procuring agency will proceed to the next lowest evaluated bid to make a similar determination of that Bidder's capabilities to perform satisfactorily.

**28. Award Criteria**

- 28.1 Subject to ITB Clause 30, the Procuring agency will award the contract to the successful Bidder whose bid has been determined to be substantially responsive and has been determined to be the lowest evaluated bid, provided further that the Bidder is determined to be qualified to perform the contract satisfactorily.

**29. Procuring agency's Right to Vary**

- 29.1 The Procuring agency 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 originally specified in the Schedule

<b>Quantities at Time of Award</b>		of Requirements without any change in unit price or other terms and conditions.
<b>30. Procuring agency's Right to Accept any Bid and to Reject any or All Bids</b>	30.1	The Procuring agency reserves the right to accept or reject any bid, and 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 or any obligation to inform the affected Bidder or bidders of the grounds for the Procuring agency's action.
<b>31. Notification of Award</b>	31.1	Prior to the expiration of the period of bid validity, the Procuring agency will notify the successful Bidder in writing by registered letter or by cable, to be confirmed in writing by registered letter, that its bid has been accepted.
	31.2	The notification of award will constitute the formation of the Contract.
	31.3	Upon the successful Bidder's furnishing of the performance security pursuant to ITB Clause 33, the Procuring agency will promptly notify each unsuccessful Bidder and will discharge its bid security, pursuant to ITB Clause 15.
<b>32. Signing of Contract</b>	32.1	At the same time as the Procuring agency notifies the successful Bidder that its bid has been accepted, the Procuring agency will send the Bidder the Contract Form provided in the bidding documents, incorporating all agreements between the parties.
	32.2	Within Ten (10) days of receipt of the Contract Form, the successful Bidder shall sign and date the contract and return it to the Procuring agency.
<b>33 Performance Security</b>	33.1	Within Ten (10) days of the receipt of notification of award from the Procuring agency, the successful Bidder shall furnish the performance security in accordance with the Conditions of Contract, in the Performance Security Form provided in the bidding documents, or in another form acceptable to the Procuring agency.
	33.2	Failure of the successful Bidder to comply with the requirement of ITB Clause 32 or ITB Clause 33.1 shall constitute sufficient grounds for the annulment of the award and forfeiture of the bid security, in which event the Procuring agency may make the award to the next lowest evaluated Bidder or call for new bids.
<b>34. Corrupt or Fraudulent Practices</b>	34.1	The Government of Khyber Pakhtunkhwa requires that Procuring agency's (including beneficiaries of donor agencies' loans), as well as Bidders/Suppliers/Contractors under Government-financed contracts, observe the highest standard of ethics during the procurement and execution of such contracts. In pursuance of this policy, the KPPRA, in accordance with the KPP Act, 2012 and Rules made thereunder: <ul style="list-style-type: none"> <li>a. defines, for the purposes of this provision, the terms set forth below as follows: <ul style="list-style-type: none"> <li>i. "corrupt practice" means the offering, giving, receiving or soliciting of anything of value to influence the action of a public official in the procurement process or in contract execution; and</li> </ul> </li> </ul>



- ii. “fraudulent practice” means a misrepresentation of facts in order to influence a procurement process or the execution of a contract to the detriment of the Procuring agency, and includes collusive practice among Bidders (prior to or after bid submission) designed to establish bid prices at artificial non-competitive levels and to deprive the Procuring agency of the benefits of free and open competition;
  - b. will reject a proposal for award if it determines that the Bidder recommended for award has engaged in corrupt or fraudulent practices in competing for the contract in question;
  - c. will declare a firm ineligible, either indefinitely or for a stated period of time, to be awarded a Government-financed contract if it at any time determines that the firm has engaged in corrupt or fraudulent practices in competing for, or in executing, a Government-financed contract.
- 34.2 Furthermore, Bidders shall be aware of the provision stated in sub-clause 5.4 and sub-clause 24.1 of the General Conditions of Contract.
- 35. Integrity Pact** 35.1 The Bidder shall sign and stamp the Integrity Pact provided at Bid Form-5 to Bid in the Bidding Document for all Provincial Government procurement contracts exceeding Rupees ten million. Failure to such Integrity Pact shall make the bidder non-responsive.
- 36. Applicable Bidding Procedure** 36.1 The bidding procedure shall be single stage two envelopes procedure as provided under Rule 6 2 (b) of Khyber Pakhtunkhwa Procurement Rules, 2014 as mentioned in ITB Bidders are also advised to refer to the Bid Data Sheet to confirm the Bidding procedure applicable in the instant bidding process.
- 36.2
- 36.3 The “Single stage – Two Envelop bidding procedure” is explained below:
- i. The bid shall comprise a single package containing two separate envelopes. Each envelope shall contain separately the financial proposal and the technical proposal;
  - ii. the envelopes shall be marked as “FINANCIAL PROPOSAL” and “TECHNICAL PROPOSAL” in bold and legible letters to avoid confusion;
  - iii. initially, only the envelope marked “TECHNICAL PROPOSAL” shall be opened;
  - iv. the envelope marked as “FINANCIAL PROPOSAL” shall be retained in the custody of Procuring Agency without being opened;
  - v. the Procuring Agency shall evaluate the technical proposal, without reference to the price and reject any proposal which do not conform to the specified requirements;
  - vi. during the technical evaluation no amendments in the technical proposal shall be permitted;
  - vii. the financial proposals of bids shall be opened publicly at a time, date and venue to be announced and communicated to the Bidders in advance;
  - viii. After the evaluation and approval of the technical proposal the Procuring Agency shall at a time within the bid validity period,

publicly open the financial proposals of the technically accepted bids only. The financial proposal of bids found technically non-responsive shall be returned un-opened to the respective Bidders; and

ix. The bid found to be the lowest evaluated bid shall be accepted.

Technical proposal shall not have any reference to price or the amount of bid security. The bid security shall only be attached with Financial Proposals.

37. Bid Price
- 37.1 Prices shall be quoted on DAP<sup>1</sup> basis in Pak Rupee. For purpose of comparison of the bids quoted in different currencies the price shall be converted in Pak Rupees and the rate of exchange shall be the selling rate prevailing on the date of opening of financial bids as notified by the state bank of Pakistan on that day.
- DAP (including insurance and customs clearance if applicable) to final destination identified in the Bid Data Sheet.
- 37.2 Prices shall also be quoted as specified in each Price Schedule included in Section VIII, Sample Forms. The disaggregation of price components is required solely for the purpose of facilitating the comparison of bids by the Procuring Agency. This shall not in any way limit the Procuring Agency's right to contract on any of the terms offered.
- 37.3 The terms DAP, EXW, CPT, CFR, etc., shall be governed by the rules prescribed in the current edition of INCOTERMS 2010 published by the International Chamber of Commerce, Paris subject to the INCOTERMS not in contradiction to the local financial regulations.
- 37.4 The Bidder's separation of price components in accordance with ITB Clause 37.2 above will be solely for the purpose of facilitating the comparison of bids by the Procuring Agency and will not in any way limit the Procuring Agency's right to contract on any of the terms offered.
- 37.5 Unless otherwise specified in the Bid Data Sheet, prices quoted by the Bidder shall be fixed 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. If so indicated in the Bid Data Sheet, bids are being invited for one or more items, or for individual Contracts (lots). Each item offered must comprise the full quantity required under that item. Bidders wishing to offer any price reduction for the award of more than one Contract shall specify in their bid the price reductions applicable to each package or, alternatively, to individual Contracts within the package. Price reductions may be submitted as an amount or a percentage to be applied to the bid prices.
- 37.6 Form prescribed for quoting of prices is to be filled in very carefully, preferably typed. Any alteration/ correction must be initialed. Every page is to be signed and stamped at the bottom. Serial number of the quoted item may be marked with red/yellow marker.
- 37.7 The Bidder should quote the prices of goods according to the technical specifications of this document. The technical specifications of goods, different from the required specifications, shall straightway be rejected.
- 37.8 The Bidder is required to offer a competitive price. All prices must include the taxes and duties, where applicable. If there is no mention of

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<sup>1</sup> Incoterms 2010 will apply

taxes, the offered/ quoted price shall be considered as inclusive of all prevailing taxes/ duties.

- 37.9 The benefit of exemption from or reduction in the taxes and duties shall be passed on to the Procuring Agency.

Being government supplies, contraceptive commodities are exempted from taxes and duties for which the relevant procuring department will provide necessary exemptions / NOCs to bidders for custom clearance against imported consignments.

- 37.10 Prices offered should be for the entire quantity of an item demanded in the Schedule of Requirement; partial quantity offers shall straightaway be rejected. Conditional offer shall also be considered as non-responsive Bid

- 37.11 While making a price quote, trend/ inflation in the rate of goods and services in the market should be kept in mind. No request for increase in price due to market fluctuation in the cost of goods and services shall be entertained.

- 37.12 Unless otherwise specified in the Bid Data Sheet, prices quoted by the Bidder shall be fixed during the Bidder's performance of the Contract and not subject to variation on any account.

- 37.13 Advance Income tax @ 4% (or as prescribed by Govt. at that time) will be deducted at source from all the local firms registered under income tax rules with the Government of Pakistan, which will not be applicable to international firms.

38. Bidding for  
Selective Items

- 38.1 A Bidder is authorized to bid for one or all the items mentioned in the Schedule of Requirements provided it fulfills the prerequisite for that particular item/items.

However, bid for partial quantities of an item in the Schedule of requirement is not allowed. THE BID FOR MORE THAN ONE ITEM SHALL BE FOR THE WHOLE QUANTITY OF THAT ITEM.

**PART ONE**  
**SECTION - II**

**GENERAL CONDITIONS  
OF THE CONTRACT**

## **General Conditions of Contract**

### **1. Definitions**

- 1.1 In this Contract, the following terms shall be interpreted as indicated:
- a. “The Contract” means the agreement entered into between the Procuring agency and the Supplier, as recorded in the Contract Form 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. “The Goods” means all of the equipment, machinery, and/or other materials which the Supplier is required to supply to the Procuring agency under the Contract.
  - d. “The Services” means those services ancillary to the supply of the Goods, such as transportation and insurance, and any other incidental services, such as installation, commissioning, provision of technical assistance, training, and other such obligations of the Supplier covered under the Contract.
  - e. “GCC” means the General Conditions of Contract contained in this section.
  - f. “SCC” means the Special Conditions of Contract.
  - g. “The Procuring agency” means the organization purchasing the Goods, as named in SCC.
  - h. “The Procuring agency’s country” is the country named in SCC.
  - i. “The Supplier” means the individual or firm supplying the Goods and Services under this Contract.
  - j. “The Project Site,” where applicable, means the place or places named in SCC.
  - k. “Day” means calendar day.

### **2. Application**

- 2.1 These General Conditions shall apply to the extent that they are not superseded by provisions of other parts of the Contract.

### **3. Country of Origin**

- 3.1 All Goods and Services supplied under the Contract shall have their origin in the countries and territories eligible under the rules and 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.
<b>4. Standards</b>	4.1	The Goods supplied under this Contract shall conform to the standards mentioned in the Technical Specifications, 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.
<b>5. Use of Contract Documents and Information; Inspection and Audit by the Government</b>	5.1	The Supplier shall not, without the Procuring agency'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 Procuring agency 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 Procuring agency's prior written consent, make use of any document or information enumerated in GCC Clause 5.1 except for purposes of performing the Contract.
	5.3	Any document, other than the Contract itself, enumerated in GCC Clause 5.1 shall remain the property of the Procuring agency and shall be returned (all copies) to the Procuring agency on completion of the Supplier's performance under the Contract if so required by the Procuring agency.
	5.4	The Supplier shall permit the Procuring agency to inspect the Supplier's accounts and records relating to the performance of the Supplier and to have them audited by auditors appointed by the procuring agency, if so required.
<b>6. Patent Rights</b>	6.1	The Supplier shall indemnify the Procuring agency 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 Procuring agency's country.
<b>7. Performance Security</b>	7.1	Within ten (10) days of receipt of the notification of Contract award, the successful Bidder shall furnish to the Procuring agency the performance security in the amount specified in SCC.
	7.2	The proceeds of the performance security shall be payable to the Procuring agency as compensation for any loss resulting from the Supplier's failure to complete its obligations under the Contract.
	7.3	The performance security shall be denominated in the currency of the Contract acceptable to the Procuring agency and shall be in one of the following forms: <ul style="list-style-type: none"> <li>a. a bank guarantee or an irrevocable letter of credit issued by a reputable bank located in the Procuring agency's country, in the form provided in the bidding documents or another form acceptable to the Procuring agency; or</li> </ul>

b. a cashier's or certified cheque.

7.4 The performance security will be discharged by the Procuring agency and returned to the Supplier not later than thirty (30) days following the date of completion of the Supplier's performance obligations under the Contract, including any warranty obligations, unless specified otherwise in SCC.

## **8. Inspections and Tests**

8.1 The Procuring agency or its representative shall have the right to inspect and/or to test the Goods to confirm their conformity to the Contract specifications at no extra cost to the Procuring agency. SCC and the Technical Specifications shall specify what inspections and tests the Procuring agency requires and where they are to be conducted. The Procuring agency shall notify the Supplier in writing, in a timely manner, of the identity of any representatives retained for these purposes.

8.2 The inspections and tests may be conducted on the premises of the Supplier or its subcontractor(s), at point of delivery, and/or at the Goods' final destination. If conducted on the premises of the Supplier or its subcontractor(s), all reasonable facilities and assistance, including access to drawings and production data, shall be furnished to the inspectors at no charge to the Procuring agency.

8.3 Should any inspected or tested Goods fail to conform to the Specifications, the Procuring agency may reject the Goods, and the Supplier shall either replace the rejected Goods or make alterations necessary to meet specification requirements free of cost to the Procuring agency.

8.4 The Procuring agency's right to inspect, test and, where necessary, reject the Goods after the Goods' arrival in the Procuring agency's country shall in no way be limited or waived by reason of the Goods having previously been inspected, tested, and passed by the Procuring agency or its representative prior to the Goods' shipment from the country of origin.

8.5 Nothing in GCC Clause 8 shall in any way release the Supplier from any warranty or other obligations under this Contract.

## **9. Packing**

9.1 The Supplier shall provide such packing of the Goods 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.

9.2 The packing, marking, and documentation within and outside the packages shall comply strictly with such special requirements as shall be expressly provided for in the Contract, including additional requirements, if any, specified in SCC, and in any subsequent instructions ordered by the Procuring agency.

## **10. Delivery and**

10.1 Delivery of the Goods shall be made by the Supplier in accordance with

<b>Documents</b>		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 SCC.
	10.2	Documents to be submitted by the Supplier are specified in SCC.
<b>11. Insurance</b>	11.1	The Goods supplied under the Contract shall be (DAP) under which risk is transferred to the buyer after having been delivered at specified location as mentioned in the bidding documents, hence insurance coverage is seller's responsibility.
<b>12. Transportation</b>	12.1	The Supplier is required under the Contract to transport the Goods to a specified place of destination within the Procuring agency's country, transport to such place of destination in the Procuring agency's country, including insurance and storage, as shall be specified in the Contract, shall be arranged by the Supplier, and related costs shall be included in the Contract Price.
<b>13. Incidental Services</b>	13.1	<p>The Supplier may be required to provide any or all of the following services, including additional services, if any, specified in SCC:</p> <ul style="list-style-type: none"> <li>a. performance or supervision of on-site assembly and/or start-up of the supplied Goods;</li> <li>b. furnishing of tools required for assembly and / or maintenance of the supplied Goods;</li> <li>c. furnishing of a detailed operations and maintenance manual for each appropriate unit of the supplied Goods;</li> <li>d. performance or supervision or maintenance and/or repair of the supplied Goods, for a period of time agreed by the parties, provided that this service shall not relieve the Supplier of any warranty obligations under this Contract; and</li> <li>e. training of the Procuring agency's personnel, at the Supplier's plant and/or on-site, in assembly, start-up, operation, maintenance, and/or repair of the supplied Goods.</li> </ul>
	13.2	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 for other parties by the Supplier for similar services.
<b>14. Spare Parts</b>	14.1	<p>As specified in SCC, the Supplier may be required to provide any or all of the following materials, notifications, and information pertaining to spare parts manufactured or distributed by the Supplier:</p> <ul style="list-style-type: none"> <li>a. such spare parts as the Procuring agency may elect to purchase from the Supplier, provided that this election shall not relieve the Supplier of any warranty obligations under the Contract; and</li> <li>b. in the event of termination of production of the spare parts: <ul style="list-style-type: none"> <li>i. advance notification to the Procuring agency of the pending termination, in sufficient time to permit the Procuring agency to procure needed requirements;</li> </ul> </li> </ul>



- ii. following such termination, furnishing at no cost to the Procuring agency, the blueprints, drawings, and specifications of the spare parts, if requested.

## **15. Warranty**

- 15.1 The Supplier warrants that the Goods supplied under the Contract are new, unused, of the most recent or current models, and that they incorporate all recent improvements in design and materials unless provided otherwise in the Contract. The Supplier further warrants that all Goods supplied under this Contract shall have no defect, arising from design, materials, or workmanship (except when the design and/or material is required by the Procuring agency's specifications) or from any act or omission of the Supplier, that may develop under normal use of the supplied Goods in the conditions prevailing in the country of final destination.
- 15.2 This warranty shall remain valid for twelve (12) months after the Goods, or any portion thereof as the case may be, have been delivered to and accepted at the final destination indicated in the Contract, or for eighteen (18) months after the date of shipment from the port or place of loading in the source country, whichever period concludes earlier, unless specified otherwise in SCC.
- 15.3 The Procuring agency shall promptly notify the Supplier in writing of any claims arising under this warranty.
- 15.4 Upon receipt of such notice, the Supplier shall, within the period specified in SCC and with all reasonable speed, repair or replace the defective Goods or parts thereof, without costs to the Procuring agency.
- 15.5 If the Supplier, having been notified, fails to remedy the defect(s) within the period specified in SCC, within a reasonable period, the Procuring agency may proceed to take such remedial action as may be necessary, at the Supplier's risk and expense and without prejudice to any other rights which the Procuring agency may have against the Supplier under the Contract.

## **16. Payment**

- 16.1 The method and conditions of payment to be made to the Supplier under this Contract shall be specified in SCC.
- 16.2 The Supplier's request(s) for payment shall be made to the Procuring agency in writing, accompanied by an invoice describing, as appropriate, the Goods delivered and Services performed, and by documents submitted pursuant to GCC Clause 10, and upon fulfillment of other obligations stipulated in the Contract.
- 16.3 Payments shall be made promptly by the Procuring agency, but in no case later than sixty (60) days after submission of an invoice or claim by the Supplier.
- 16.4 The currency of payment is Pak. Rupees.

## **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 SCC or in the Procuring agency's request for bid validity

extension, as the case may be.

## **18. Change Orders**

- 18.1 The Procuring agency may at any time, by a written order given to the Supplier pursuant to GCC Clause 31, make changes within the general scope of the Contract in any one or more of the following:
- a. drawings, designs, or specifications, where Goods to be furnished under the Contract are to be specifically manufactured for the Procuring agency;
  - b. the method of shipment or packing;
  - c. the place of delivery; and/or
  - d. the Services to be provided by the Supplier.
- 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 Procuring agency'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. Assignment**

- 20.1 The Supplier shall not assign, in whole or in part, its obligations to perform under this Contract, except with the Procuring agency's prior written consent.

## **21. Subcontracts**

- 21.1 The Supplier shall notify the Procuring agency in writing of all subcontracts awarded under this Contract if not already specified in the bid. Such notification, in the original bid or later, shall not relieve the Supplier from any liability or obligation under the Contract.
- 21.2 Subcontracts must comply with the provisions of GCC Clause 3.

## **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 Procuring agency 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 Procuring agency 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 Procuring agency 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 Procuring agency 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 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 SCC. Once the maximum is reached, the Procuring agency may consider termination of the Contract pursuant to GCC Clause 24.

**24. Termination for Default**

- 24.1 The Procuring agency, 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 Procuring agency pursuant to GCC Clause 22; or
  - b. if the Supplier fails to perform any other obligation(s) under the Contract.
  - c. if the Supplier, in the judgment of the Procuring agency has engaged in corrupt or fraudulent practices in competing for or in executing the Contract.

For the purpose of this clause:

“corrupt practice” means the offering, giving, receiving or soliciting of any thing of value to influence the action of a public official in the procurement process or in contract execution.

“fraudulent practice” means a misrepresentation of facts in order to influence a procurement process or the execution of a contract to the detriment of the Borrower, and includes collusive practice among Bidders (prior to or after bid submission) designed to establish bid prices at artificial non-competitive levels and to deprive the Borrower of the benefits of free and open competition.

- 24.2 In the event the Procuring agency terminates the Contract in whole or in part, pursuant to GCC Clause 24.1, the Procuring agency 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 Procuring agency 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 Procuring agency in its sovereign capacity, wars or revolutions, fires, floods, epidemics, quarantine restrictions, and freight embargoes.
	25.3	If a Force Majeure situation arises, the Supplier shall promptly notify the Procuring agency in writing of such condition and the cause thereof. Unless otherwise directed by the Procuring agency in writing, the Supplier shall continue to perform its obligations under the Contract as far as is reasonably practical, and shall seek all reasonable alternative means for performance not prevented by the Force Majeure event.
<b>26. Termination for Insolvency</b>	26.1	The Procuring agency 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 which has accrued or will accrue thereafter to the Procuring agency.
<b>27. Termination for Convenience</b>	27.1	The Procuring agency, 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 Procuring agency’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	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 Procuring agency at the Contract terms and prices. For the remaining Goods, the Procuring agency may elect: <ul style="list-style-type: none"> <li>a. to have any portion completed and delivered at the Contract terms and prices; and/or</li> <li>b. to cancel the remainder and pay to the Supplier an agreed amount for partially completed Goods and Services and for materials and parts previously procured by the Supplier.</li> </ul>
<b>28. Resolution of Disputes</b>	28.1	The Procuring agency and the Supplier shall make every effort to resolve amicably by direct informal negotiation any disagreement or dispute arising between them under or in connection with the Contract.
	28.2	If, after thirty (30) days from the commencement of such informal negotiations, the Procuring agency and the Supplier have been unable to resolve amicably a Contract dispute, either party may require that the dispute be referred for resolution to the formal mechanisms specified in SCC. These mechanisms may include, but are not restricted to, conciliation mediated by a third party, adjudication in an agreed manner and/or arbitration.
<b>29. Governing Language</b>	29.1	The Contract shall be written in the language specified in SCC. Subject to GCC Clause 30, the version of the Contract written in the specified language shall govern its interpretation. All correspondence and other documents pertaining to the Contract which are exchanged by the parties shall be written in the same language.

<b>30. Applicable Law</b>	30.1	The Contract shall be interpreted in accordance with the laws of the Procuring agency's country, unless otherwise specified in SCC.
<b>31. Notices</b>	31.1	Any notice given by one party to the other pursuant to this Contract shall be sent to the other party in writing or by cable, telex, or facsimile and confirmed in writing to the other party's address specified in SCC.
	31.2	A notice shall be effective when delivered or on the notice's effective date, whichever is later.
<b>32. Taxes and Duties</b>	32.1	Supplier shall be entirely responsible for all applicable taxes, duties, license fees, cess etc., incurred until delivery of the contracted Goods to the Procuring agency.

## **PART TWO (PROCUREMENT SPECIFIC PROVISIONS)**

- **Invitation for Bids (IFB)**
- **Bid Data Sheet (BDS)**
- **Special Conditions of Contract (SCC)**
- **Schedule of Requirements**
- **Technical Specifications**
- **Sample Forms**

## **PART TWO**

### **SECTION I - Invitation for Bids**



## Health and Population Welfare Departments Government of Khyber Pakhtunkhwa

### Invitation for Bids (IFB) (Re Tender)

#### Joint Procurement of Contraceptives (2019-20)

Health & Population Welfare Departments, including Merged Districts, Government of Khyber Pakhtunkhwa, Pakistan jointly invites sealed bids from eligible bidders for supply of following contraceptive items through Single Stage – Two Envelopes bidding procedure as per Rule 6(2)(b) of Khyber Pakhtunkhwa Public Procurement Rules 2014.

1. Male Latex Condoms
2. Intra Uterine Contraceptive Device (IUCD)
3. Implants (single and Double rod)

The detailed description and schedule of requirement of above contraceptives are given in the Standard Bidding Documents. (Imported & Local)

Interested eligible bidders may obtain Bidding Documents from the address mentioned below upon submission of written application along with payment of non-refundable fee of PKR.1000.00 (One Thousand only) by Bank Draft /Cash in favour of Project Director Integrated Health Project, Directorate General Health Services, Peshawar. Interested Bidders can submit bid for single or more items (separately) against full quantities as given in the bidding documents, however, evaluation of bids and award of contract shall be made on single item basis.

Bidding documents will be available from the date of advertisement and SBDs will be issued up to 20-04-2020 at 10:30 AM. Bidding documents are also available on the website of Procuring Departments ([www.healthkp.gov.pk](http://www.healthkp.gov.pk)).

Sealed Bids must reach at the address given below on or before 20-04-2020 at 10:30 AM and will be opened in the presence of the bidders/representatives who choose to be present on the same day at 11:00 AM.

Bid security five hundred thousand only (Rs. 500,000/-) for each item (under framework mode of procurement method) in the shape of Call Deposit or any other financial instrument permissible under KPPRA Rules in PKR in favor of Project Director Integrated Health Project, Directorate General Health Services, Khyber Pakhtunkhwa Peshawar issued from any scheduled Bank of Pakistan must be attached with financial bid. Late bids will not be entertained.

A pre-bid meeting shall be held on 14-04-2020 at 11:00 AM at the Conference Room of Directorate General Health Services, Ex-FATA Secretariat, Warsak Road Peshawar.

The bidders are requested to quote their best and final prices as no negotiations on the price are allowed.

The procuring agency reserves the right to reject any or all the bids under clause 47 of KPPRA procurement rules 2014.

Project Director Integrated Health Project  
Directorate General Health Services /  
Khyber Pakhtunkhwa, Peshawar.  
Phone: +92-91-9216342-5,  
Fax: +92-91-9216346,  
e-mail: [ihphealthkp@gmail.com](mailto:ihphealthkp@gmail.com)

**PART TWO**  
**SECTION - II**

**BID DATA SHEET**



## Bid Data Sheet

ITB Ref	Description	Detail
	Commencement of sale of Bidding Document	From the date of publishing of IFB
ITB Clause 1.1	Name of Procuring Agency	Department of Health and Population Welfare Department Govt: Khyber Pakhtunkhwa
ITB Clause 1.1	Bid title and reference number	Bid Reference No: JPC/2019-20/01 Joint Procurement of Contraceptive for Health and Population Welfare Departments including newly merged districts
ITB Clause 1.1	Source of funds	Provincial consolidated fund for PWD, ADP + DFID for Integrated Health Project.
ITB Clause 6.1	Clarification of Bidding Documents / Procuring agency's address, telephone, Telex and facsimile, numbers.	Project Director Integrated Health Project, Health Department, Khyber Pakhtunkhwa Peshawar. Address: 37-D, Circular lane, University Town Peshawar Tel No: 091-9216342 Fax No: 091-9216346 Email: ihphealthkp@gmail.com
ITB Clause 8.1	Language of bid	English
ITB Clause 11.4	Bid Price	Price quoted shall be fixed and inclusive of all taxes, transportation, loading unloading etc.
ITB Clause 13	Documents Establishing Qualifications of Bidder	See Bid Cover Sheet and all others in Section VII. Bid Forms
ITB Clause 14.1	Documents Establishing Conformity to Bidding Documents	see list of documents at ITB 5.1 & 5.2
ITB Clause 15.1	Amount of bid security	Rs. 500,000/- for each product under Framework agreement mode of procurement
ITB Clause 16.1	Bid validity period	<b>30 June 2020</b>
ITB Clause 17.1	Number of bid copies	One original set and 1(one) copy

ITB Clause 17.2	Marking of Bids	Project Director Integrated Health Project, Joint Procurement of Contraceptive for Health and Population Welfare Departments
ITB Clause 18.2	Address for bid submission	Project Director Integrated Health Project, Health Department, Khyber Pakhtunkhwa Peshawar. Address: 37-D, Circular lane, University Town Peshawar
ITB Clause 19.1	Last date and time for the receipt of bidding document	As per IFB
ITB Clause 19.3	Pre-Bid meeting with the bidders	As per IFB
ITB Clause 20.1	Late submission of bids	Any bid received by the Procuring agency after the deadline for submission of bids will be rejected and returned unopened to the Bidder.
ITB Clause 22.1	Date, time and venue of opening of bids	As per IFB
ITB Clause 25.3	Criteria for bid evaluation	Merit Point Evaluation The items ranked highest in merit points (obtained through and based on technical and financial evaluation) will be declared as successful bid.
ITB Clause 29.1	Right to Vary Quantities at Time of Award	Increase or decrease in the quantities permissible under the rules.
ITB Clause 36.1	Bidding procedure	Single stage – Two Envelop procedure as detailed at ITB 10.1
ITB Clause 37	Bid Price: Final Destination	DAP - Central Warehouse and Supplies, Karachi
ITB Clause 37.10	Bid Price	Bidder must quote for the full quantities requested

**PART TWO**  
**SECTION - III**

**SPECIAL CONDITIONS**  
**OF CONTRACT**  
**(SCC)**

## 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.

[Instructions for completing the Special Conditions of Contract are provided, as needed, in the notes in italics mentioned for the relevant SCC. Where sample provisions are furnished, they are only illustrative of the provisions that the Procuring agency should draft specifically for each procurement.]

### 1. Definitions (GCC Clause 1)

GCC 1.1 (g)—The Procuring agency is: Health and Population Welfare Department including merged districts Khyber Pakhtunkhwa

GCC 1.1 (h)—The Procuring agency's country is: Pakistan

GCC 1.1 (i)—The Supplier is:

#### Sample Provision

GCC 1.1 (j)—The Project Site is: *[if applicable]* Not Applicable

#### 1. The Contract

- 1.1 The following documents shall be deemed to form and be read and construed as integral part of the Contract ,:-
  - a. the Schedule of Requirements.
  - b. the Technical Specifications.
  - c. the Price Schedule submitted by the Bidder.
  - d. the Procuring Agency's Notification of Award.
  - e. the Purchase Order
  - f. the General Conditions of Contract
  - g. Special Conditions of Contract
- 1.2 Both Health and Population Welfare Departments including merged districts will sign individual contracts with the selected bidder(s) separately against the indicated quantities in schedule of requirement.
- 1.3 The Contract words and expressions shall have the same meanings as are respectively assigned to them in the General Conditions of Contract
- 1.4 The contract shall remain valid for one year from the date of signing, unless amended by mutual consent
- 1.5 The contract is to be made on stamp paper of an amount required as per law.

### 2. Country of Origin (GCC Clause 3)

All countries and territories as indicated in Part Two Section VI of the bidding documents, "Eligibility for the Provisions of Goods, Works, and Services in Government-Financed Procurement".

### 3. Performance Security (GCC Clause 7)

GCC 7.1—The amount of performance security, as a percentage of the Contract Price, shall be:

The Supplier, prior to signing of this contract, shall provide to the respective Procuring Agency separately a Performance Guarantee, in a manner acceptable to the procuring agency, equivalent to 10% of the Contract amount on the prescribed format and in prescribed manner. This Performance Guarantee shall be released to the Supplier upon successful completion of the Contract i.e. One (1) Year from the receipt of products.

Supplier's Bid Security already submitted with the Bid shall only be released upon satisfactory submission of a Performance Guarantee in accordance with sub-clause (i) above  
Failure to submit a Performance Guarantee shall result into forfeiture of Bid Security and Cancellation of Contract and initiation of blacklisting procedure.

*[The following provision should be used in the case of Goods having warranty obligations.]*

GCC 7.4—After delivery and acceptance of the Goods, the performance security shall be reduced to eight (8) percent of the Contract Price to cover the Supplier's warranty obligations in accordance with Clause GCC 15.2.

#### **4. Inspections and Tests (GCC Clause 8)**

GCC 8.6—Inspection and tests prior to shipment of Goods and at final acceptance are as follows:

- i. For imported items, acceptable quality report from WHO/UNFPA prequalified lab for testing contraceptives is mandatory for each batch supplied<sup>2</sup>. However, any subsequent testing after the commodities received by the Department shall be the responsibility of the purchasing entity.
- ii. After delivery of contraceptives (Locally manufactured commodities) at the Procuring Agency's premises, the Procuring Agency shall send the samples from each batch to the Drugs Testing Laboratory, Khyber Pakhtunkhwa/Central Drug Testing Laboratory Karachi, for testing. The Inspection Committee constituted by the Procuring Agency shall inspect the quantity, specifications of goods after receipt of standard quality report from DTL concerned. In addition, the Procuring Agency, if required, may send samples from up to five (5) batches abroad to a WHO prequalified lab for testing purposes. The cost of the lab tests shall be borne by the Supplier.

In case of substandard/or not in accordance with Drug Act.1976 report of any batch the Supplier has the right to go for appellate laboratory. If it is again declared substandard, the Supplier will be intimated and they will be bound to re-supply the entire fresh stock of that batch free of cost within the reasonable time period to be intimated by the Procuring Agency but not later than 21 days (three weeks) from the date of intimation, which will be subject to completion of all testing and verification formalities. At the parallel, the case will also be forwarded to the Drugs Regulatory Authority for legal action as per Drugs Act 1976 and substandard stock will not be returned to the supplier. The same will be destroyed in front of the committee so constituted for each such case.

The Inspection Committee will carry out detailed physical examination of stocks and can reject, even if it is declared of standard quality by DTL, if found not according to the approved sample and other technical specifications like packaging, labeling, printing and quantity etc. Moreover, the Supplier will also be responsible to replace the unconsumed expired stores without any further charges.

#### **Shelf life**

The remaining shelf life must be minimum of 85% for the locally manufactured contraceptives and 75% for the imported contraceptives when delivered at the Central Warehouse and Supplies Karachi.

#### **5. Packing (GCC Clause 9)**

##### **Labeling and Packing**

- i. The manufacturer shall follow the Drugs (Labelling and Packing) Rules 1986, framed under the Drugs Act, 1976 and DRAP Act 2012 and rules framed thereunder.

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<sup>2</sup> Evaluation criteria (1) WHO prequalification certificate for international bidders / imported items and Evaluation criteria (2) Batch Inspection certificate from any of the WHO prequalified labs for locally manufactured products

- ii. However, the name of Contraceptive (Generic & Brand), equally prominent, should be printed/ written in indelible ink both in English and Urdu on the outer cartons and on each Pack, Blister, Tubes, Vial etc. Besides the name and principal place of business of the Manufacturer, the drug manufacturing license No., manufacturing date i.e. (MM/YYYY), expiry date (MM/YYYY), registration No., batch No., and Urdu version namely: name of drug, dosage and instructions, should also be written on the outer carton and on the inner most container in bold letters. Expiry date must be printed on each immediate container.
- c) Additional instructions for packing
- i. The suppliers are required to furnish the Warranty certificate with regard to the potency and stability (Including coloration of medicines) of the Drug for human consumption etc. in accordance with the Drugs Act, 1976 and DRAP Act 2012 as per prescribed format.
  - ii. The bidder shall supply the Contraceptives in special green packing with Logo of the Government of Khyber Pakhtunkhwa. The following wording/insignia shall be printed in bold letters both in Urdu & English in indelible red color ink on each carton, pack, blister, vial / ampoule and immediate container etc.
    - a. For Department of Health:
 

“NOT FOR SALE”  
“DOH: Govt. of Khyber Pakhtunkhwa”
    - b. For Population Welfare Department:
 

“NOT FOR SALE”  
“PWD: Govt. of Khyber Pakhtunkhwa”
  - iii. Due to the small ordered quantities, the green color is not mandatory for implants however, the master cartons and inner packs must be printed/stamped with special instructions given in c ii above even after arrival at the central warehouse, Karachi.
  - iv. After award of the contract, the Supplier shall submit the samples of finished artwork in accordance with the above instructions for approval of the concerned Procuring Agency.
  - v. Art work will be given with supply order and successful bidder is bound to provide the color pack scheme of art work in compliance to the instruction given in SBD within one week of issuance of supply order.

## 6. **Delivery and Documents (GCC Clause 10)**

### **Sample provision (DAP terms)**

GCC 10.3—Upon shipment, the Supplier shall notify the Procuring agency the full details of the shipment, including Contract number, description of Goods, quantity and usual transport document. The Supplier shall provide the following documents to the Procuring agency:

- i. copies of the Supplier’s invoice showing Goods’ description, quantity, unit price, and total amount;
- ii. original and two copies of the usual transport document (for example, a negotiable bill of lading, a non-negotiable sea waybill, an inland waterway document, an air waybill, a railway consignment note, a road consignment note, or a multimodal transport document whichever applicable) which the buyer may require to take the goods;
- iii. copies of the packing list identifying contents of each package;
- iv. insurance certificate;
- v. Manufacturer’s or Supplier’s warranty certificate;

- vi. inspection certificate, issued by the WHO/UNFPA Prequalified Lab, and the Supplier's factory inspection report / Certificate of analysis / Quality Assurance Certificate; and
- vii. certificate of origin.

#### Transportation/Delivery Requirements

- i. The Supplier shall arrange such transportation of the contraceptives as is required to prevent their damage or deterioration during transit to their final destination and in accordance with the terms and manner prescribed in the Schedule of Requirement
- ii. The Supplier will be wholly responsible, at their risk and cost, for unloading the contraceptives at the Central Warehouse and Supplies Karachi and if the contraceptives are delivered by container, for de-stuffing the container(s) and removing the empty container(s) from the Site. All costs associated with the transportation including loading/unloading of contraceptives and road taxes shall be borne by the Supplier.
- iii. All **cold chain (perishable)** items must be delivered in a safe and proper manner, prescribed for such types of items if applicable.

#### 7. Insurance (GCC Clause 11)

GCC 11.1— The Goods supplied under the Contract shall be delivery through incoterm Delivery At Place i.e. Central Warehouse and Supplies Karachi(DAP) under which risk is transferred to the buyer after having been delivered to Central Warehouse and Supplies Karachi , hence marine and other insurance coverage is sellers responsibility. Since the Insurance is seller's responsibility they may arrange appropriate coverage.

#### 8. Incidental Services (GCC Clause 13)

GCC 13.1—Incidental services to be provided are: Not Applicable

*[Selected services covered under GCC Clause 13 and/or other should be specified with the desired features. The price quoted in the bid price or agreed with the selected Supplier shall be included in the Contract Price.]*

#### 9. Spare Parts (GCC Clause 14)

GCC 14.1—Additional spare parts requirements are: Not Applicable

##### Sample provision

GCC 14.1—Supplier shall carry sufficient inventories to assure ex-stock supply of consumable spares for the Goods. Other spare parts and components shall be supplied as promptly as possible, but in any case within six (6) months of placing the order and opening the letter of credit.

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

##### Sample provision

GCC 15.2—In partial modification of the provisions, the warranty period shall be   12   months from date of acceptance of the Goods. The Supplier shall, in addition, comply with the performance and/or consumption guarantees specified under the Contract. If, for reasons attributable to the Supplier, these guarantees are not attained in whole or in part, the Supplier shall, at its discretion, either:

- a. make such changes, modifications, and/or additions to the Goods or any part thereof as may be necessary in order to attain the contractual guarantees specified in the Contract at its

own cost and expense and to carry out further performance tests in accordance with SCC 4,

or

b. pay liquidated damages to the Procuring agency with respect to the failure to meet the contractual guarantees.

GCC 15.4 & 15.5—The period for correction of defects in the warranty period is half of the delivery period.

## **11. Payment (GCC Clause 16)**

### **Sample provision**

GCC 16.1—The method and conditions of payment to be made to the Supplier under this Contract shall be as follows:

#### **Payment for Goods supplied:**

The Procuring Agency shall make the payment to the Supplier in consideration of the provision of the Goods and Services, as specified in the Schedule of Requirements and Technical Specification in accordance with the Price Schedule submitted by the Supplier, the amount against the delivered items or such other sum as may become payable under the provisions of this Contract at the time and in the manner prescribed by this Contract

i. 100% payment shall be made upon receipt of successful deliveries followed by Batch/Lot testing report from WHO accredited lab, real time test reports showing stability study of the commodities generally manufactured by the supplier, compliance of quality standards etc. and successful inspection report of the designated Inspection Committee for imported contraceptives.

ii. For locally manufactured items, 100% payment shall be made upon receipt of successful deliveries followed by provision of Standard Laboratory Test Reports by concerned DTL, successful inspection report of the designated Inspection Committee.

## **12. Prices (GCC Clause 17)**

### **Sample provision**

GCC 17.1—Prices shall be adjusted in accordance with provisions in the Attachment to SCC. *[To be inserted only if price is subject to adjustment.]*

The Supplier shall provide to the Procuring Agency the items on the agreed cost more specifically described in the Price Schedule Submitted by the Bidder Bid form 4

Each Items supplied shall strictly conform to the Schedule of Requirements (Section IV) and to the Technical Specification (Section V) prescribed by the Procuring Agency against each item

The Unit Cost agreed in the Price Schedule Bid form 4 , is inclusive of all taxation and costs associated with transportation and other agreed incidental costs

## **13. Liquidated Damages (GCC Clause 23)**

GCC 23.1—Applicable rate:



In case the Supplier fails to make deliveries as per purchase order and within the time frame as stipulated in the Schedule of Requirement, proceedings shall be initiated against the defaulter which may result into forfeiture of the performance guarantee and blacklisting of the supplier.

In case of delay in delivery of goods beyond the periods specified in the Schedule of Requirements and subsequent purchase order, **a penalty @ 0.067% per day of the cost of late delivered supply shall be imposed upon the Supplier to the extent of 15 days (after delivery period) and @ 0.080% per day for further 15 days (Total 30 days). In case of further inordinate delay, the issue will be placed before the purchase committee for decision.**

In order for the penalty to take effect, the counting of days to start from the date of issuance of purchase order (inclusive of issuance day). Purchase order/s will be shaped accordingly as per the foregoing.

#### **14. Resolution of Disputes (GCC Clause 28)**

GCC 28.3—The dispute resolution mechanism to be applied pursuant to GCC Clause 28.2 shall be as follows:

In the case of a dispute between the Procuring agency and the Supplier, the dispute shall be referred to adjudication or arbitration in accordance with the laws of the Procuring agency's country.

The Additional Chief Secretary or his nominee shall act as sole arbitrator. The decisions taken and/or award made by the sole arbitrator shall be final and binding on the Parties.

#### **15. Governing Language (GCC Clause 29)**

GCC 29.1—The Governing Language shall be: English

#### **16. Applicable Law (GCC Clause 30)**

GCC 30.1-The Contract shall be interpreted in accordance with the laws of Islamic Republic of Pakistan which includes the following legislation:

**The Employment of Children (ECA) Act 1991**  
**The Bonded Labour System (Abolition) Act of 1992**  
**The Factories Act 1934**

#### **17. Notices (GCC Clause 31)**

GCC 31.1—Procuring agency's address for notice purposes:

For notices to Population Welfare Department use the following address:

Directorate of Population Welfare , Plot No.18 , Street No. 5, Sector E8, Phase-7, Hayatabad, Peshawar

For notices to Health Department use the following address:

Project Director, Integrated Health Project, Directorate General Health Services Khyber Pakhtunkhwa , 37-D, Circular Lane, University Town Peshawar.

—Supplier's address for notice purposes: As per agreement

#### **18. Supplier's declaration**

18.1 *The supplier shall provide integrity pact signed by the supplier and the Procuring Agency.*

18.2 *[The Supplier] certifies that it has made and shall make full disclosure of all agreements and arrangements with all persons in respect of or related to the transaction with Government of Khyber Pakhtunkhwa and has not*

- taken any action or shall not take any action to circumvent the above declaration, representation or warranty
- 18.3 *[The Supplier]* accepts full responsibility and strict liability for making any false declaration, not making full disclosure, misrepresenting facts or taking any action likely to defeat the purpose of this declaration, representation and warranty. It agrees that any Contract, right, interest, privilege or other obligation or benefit obtained or procured as aforesaid shall, without prejudice to any other right and remedies available to Procuring Agency under any law, Contract or other instrument, be voidable at the option of Procuring Agency.
- 18.4 Notwithstanding any rights and remedies exercised by Procuring Agency in this regard, *[The Supplier]* agrees to indemnify Procuring Agency for any loss or damage incurred by it on account of its corrupt business practices and further pay compensation to Procuring Agency in an amount equivalent to ten times the sum of any commission, gratification, bribe, finder's fee or kickback given by *[The Supplier]* as aforesaid for the purpose of obtaining or inducing the procurement of any Contract, right, interest, privilege or other obligation or benefit in whatsoever form from Procuring Agency

**PART TWO**  
**SECTION - IV**

**SCHEDULE OF**  
**REQUIREMENTS**

**SCHEDULE OF REQUIREMENTS OF CONTRACEPTIVES FOR LHWs**  
**PROGRAMME HEALTH DEPARTMENT, KHYBER PAKHTUNKHWA**

The supplies shall be delivered in accordance with the subsequent Purchase Orders to be issued by the respective Procuring Entity as per following schedule of requirements:

#	Products	Quantity	No. of Shipments	Delivery Period	Shelf Life <sup>1</sup>	Place of Delivery	Remarks
1	Male Latex Condoms	-----	01	120 days (100%)	75%	Central Ware house and Supplies Karachi	WHO prequalified products shall be quoted, each batch to be supplied shall be delivered with WHO accredited lab tests reports <sup>2</sup>

**Mode of Penalty**

As elaborated in accordance with the clause SCC-13 hereinabove.

<sup>1</sup> Product shelf life upon delivery shall not be less than 75% of the product's documented shelf life

<sup>2</sup> Evaluation criteria (1) WHO prequalification certificate for international bidders/imported items.

**SCHEDULE OF REQUIREMENTS OF CONTRACEPTIVES FOR POPULATION  
WELFARE DEPARTMENT, KHYBER PAKHTUNKHWA**

The supplies shall be delivered in accordance with the subsequent Purchase Orders to be issued by the respective Procuring Entity as per following schedule of requirements:

#	Products	Quantity	No. of Shipments	Delivery Period	Shelf Life Minimum <sup>1</sup>	Place of Delivery	Remarks
1	Male Latex Condoms	-----	01	120 days (100%)	75%	Central Ware house and Supplies Karachi	WHO prequalified products shall be quoted, each batch to be supplied shall be delivered with WHO accredited lab tests <sup>2</sup>
2	Intra Uterine Contraceptive Device (IUCD)	-----	01	120 days (100%)	75%		
3	Implants (Single Rod)	-----	01	120 days (100%)	75%		
4	Implants (Double Rod)	-----	01	120 days (100%)	75%		

**Mode of Penalty**

As elaborated in accordance with the clause SCC-13 hereinabove.

<sup>1</sup> Product shelf life upon delivery shall not be less than 75% of the product's documented shelf life

<sup>2</sup> Evaluation criteria (1) WHO prequalification certificate for international bidders/imported items

## **SCHEDULE OF REQUIREMENTS OF CONTRACEPTIVES FOR POPULATION WELFARE MERGED DISTRICTS KHYBER PAKHTUNKHWA**

The supplies shall be delivered in accordance with the subsequent Purchase Orders to be issued by the respective Procuring Entity as per following schedule of requirements:

#	Products	Quantity	No. of Shipments	Delivery Period	Shelf Life Minimum <sup>1</sup>	Place of Delivery	Remarks
1	Male Latex Condoms	-----	01	120 days (100%)	75%	Central ware house and Supplies Karachi	WHO prequalified products shall be quoted, each batch to be supplied shall be delivered with WHO accredited lab tests <sup>2</sup>
2	Intra Uterine Contraceptive Device (IUCD)	-----	01	120 days (100%)	75%		
3	Implants (Single Rod)	-----	01	120 days (100%)	75%		
4	Implants (Double Rod)	-----	01	120 days (100%)	75%		

### **Mode of Penalty**

As elaborated in accordance with the clause SCC-13 hereinabove.

<sup>1</sup> Product shelf life upon delivery shall not be less than 75% of the product's documented shelf life

<sup>2</sup> Evaluation criteria (1) WHO prequalification certificate for international bidders/imported items

**PART TWO**  
**SECTION - V**

**TECHNICAL**  
**SPECIFICATIONS**

# Technical Specification - Male Latex Condom<sup>3</sup>

(from WHO document “The Male Latex Condom. Specifications and Guidelines for Condom Procurement: 2010”)

*WHO prequalification certification already prevails as mandatory document be responsive in technical evaluation. The WHO certificate of prequalification will be considered to be the proof of conformity of below mentioned specifications.*

General Requirements (to be verified during prequalification)	
Materials	
General Requirements	The condoms shall be made of natural rubber latex.
Bio burden levels	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.
Biocompatibility	The Quoted product shall be biocompatible.
water-extractable protein levels	<b><i>It is recommended that manufacturers determine the water-extractable levels of proteins in their products.</i></b>

- 1 Tinkler J et al. Risk assessment of dithiocarbamate accelerator residues in latex-based medical devices: genotoxicity considerations.  
*Journal of Food Chemistry and Toxicology*, 1998, 36(9–10):849–866. For further details regarding nitrosamines, refer to Annex I.
- 2 That is, in the temperature range as per UNFPA standard.
- 3 As described in *ISO 4074*.

General Requirements (to be verified during prequalification)	
Provisional shelf-life	Pending the outcome of the real-time studies, manufacturers may estimate a provisional shelf-life using an accelerated ageing study <sup>5</sup> .
Sampling	Sample condoms from three manufacturing LOTS in accordance with Annex B of <i>ISO 4074</i> .
Conditioning	Condition condoms at $(50 \pm 2)^\circ\text{C}$ for 120 days or 180 days in accordance with the relevant annex of <i>ISO 4074</i> .
testing requirement	Assess compliance with the requirements for bursting properties, freedom from holes and package integrity specified in the relevant clauses of <i>ISO 4074</i> .  If all three LOTS of condoms remain in compliance with the requirements for bursting properties, freedom from holes and package integrity specified in the relevant clauses of <i>ISO 4074</i> for a period of <b>120 days</b> at $(50 \pm 2)^\circ\text{C}$ , a <i>provisional shelf-life of three years</i> may be assigned.  If all three LOTS of condoms remain in compliance with the requirements for bursting properties, freedom from holes and package integrity specified in the relevant clauses of <i>ISO 4074</i> for a period of <b>180 days</b> at $(50 \pm 2)^\circ\text{C}$ , a <i>provisional shelf-life of five years</i> may be assigned.
Minimum stability requirements	Condoms shall comply with the minimum stability requirements defined in the relevant clause of <i>ISO 4074</i> . Condoms meeting these minimum stability requirements can be assumed to have a provisional shelf-life of two years.
Sampling	Three LOTS sampled in accordance with <i>ISO 2859-1</i> and Annex B of <i>ISO 4074</i> .
Conditioning	Incubate samples in their individual sealed containers according to the relevant annex of <i>ISO 4074</i> : <ul style="list-style-type: none"> <li>One set for <math>168 \pm 2</math> hours at <math>(70 \pm 2)^\circ\text{C}</math>, and another set for <math>(90 \pm 1)</math> days at <math>(50 \pm 2)^\circ\text{C}</math>.</li> <li>At the end of the incubation periods, withdraw the condoms and test for airburst properties, freedom from holes and package seal.</li> <li>The incubation period at <math>(50 \pm 2)^\circ\text{C}</math> 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.</li> </ul>
testing requirement	All three LOTS of condoms shall remain in compliance with the requirements for bursting properties, freedom from holes and package integrity specified in the relevant clauses of <i>ISO 4074</i> .

<sup>3</sup> Evaluation criteria (1) WHO prequalification certificate for international bidders / imported items and Evaluation criteria (2) Batch Inspection certificate from any of the WHO prequalified labs for locally manufactured products



## Performance Requirements

The performance requirements specified here are based on the requirements of *ISO 4074*. These requirements cannot be altered. Verification of compliance with these requirements must be done as part of prequalification and the LOT-by-LOT Pre-shipment compliance testing of the product. For prequalification purposes the sampling plans specified in Annex B of *ISO 4074* shall be used. For LOT-by-LOT Pre-shipment compliance testing the sampling plans specified in Annex A of *ISO 4074* shall be used.

Performance Requirements	
Bursting volume and pressure	
Sampling	In accordance with <i>ISO 2859-1</i> General Inspection Level I. For prequalification testing at least Code Letter M as specified in Annex B of <i>ISO 4074</i> shall be used.
Testing	In accordance with test method in the relevant annex of <i>ISO 4074</i> and the relevant clause in <i>ISO 4074</i> .
Requirement	<b>Minimum bursting requirements as listed below: AQL1.5</b> <b>Volume:</b> 16.0 dm <sup>3</sup> for condoms with widths less than 50.0 mm 18.0 dm <sup>3</sup> for condoms with widths from 50.0 mm up to 55.5 mm 22.0 dm <sup>3</sup> for condoms with widths greater than or equal to 56.0 mm <b>Pressure:</b> 1.0 kPa (for all widths) The width is defined as the mean lay-flat width of 13 condoms measured in accordance with the relevant annex of <i>ISO 4074</i> at a point (75 ± 5) mm from the closed end, rounded to the nearest 0.5 mm.

5 As described in *ISO 4074*.

Performance Requirements	
Bursting volume and pressure after oven conditioning (optional: see Annex I <sup>6</sup> )	
Sampling	In accordance with <i>ISO 2859-1</i> General Inspection Level I. For prequalification testing at least Code Letter M as specified in Annex B of <i>ISO 4074</i> shall be used.
Testing	Condition the samples in accordance with the relevant annex of <i>ISO 4074</i> for $(168 \pm 2)$ hours at 70 °C. Remove from oven and keep the packages at $(25 \pm 5)$ °C until tested. Within 96 hours but no sooner than 12 hours after removal from the oven, determine the bursting volume and pressure in accordance with the test method in the relevant annex of <i>ISO 4074</i> and the relevant clause in <i>ISO 4074</i> .
Requirement	<p><b>Minimum bursting requirements as listed below: AQL1.5</b></p> <p><b>Volume:</b></p> <p>16.0 dm<sup>3</sup> for condoms with widths less than 50.0 mm</p> <p>18.0 dm<sup>3</sup> for condoms with widths from 50.0 mm up to 55.5 mm</p> <p>22.0 dm<sup>3</sup> for condoms with widths greater than or equal to 56.0 mm</p> <p><b>Pressure: 1.0 kPa (for all widths)</b></p> <p>The width is defined as the mean lay-flat width of 13 condoms measured in accordance with the relevant annex of <i>ISO 4074</i> at a point <math>(75 \pm 5)</math> mm from the closed end, rounded to the nearest 0.5 mm.</p>
Freedom from holes and visible defects	
Sampling	<p><i>ISO 2859-1</i> General Inspection Level I, but at least Code Letter M.</p> <p>For prequalification testing at least Code Letter N as specified in Annex B of <i>ISO 4074</i> shall be used.</p>
Testing	In accordance with the relevant annex of <i>ISO 4074</i> .
Requirement	<p>In accordance with test method in the relevant annex of <i>ISO 4074</i>.</p> <p>Freedom from holes: <b>AQL 0.25</b></p> <p>Critical visible defects: <b>AQL 0.4</b></p> <p>Non-critical visible defects: <b>AQL 2.5</b></p> <p><i>ISO 4074</i> describes a limited number of critical visible defects. WHO specifies an extended list of critical visible defects and a list of non-critical visible defects in Chapter 3, Clauses 2.1 and 2.2.</p> <p><b>exact definitions of critical and non-critical defects should be reviewed and agreed upon during the contractual process.</b></p>
Package seal integrity	
Sampling	<i>ISO 2859-1</i> Inspection Level S-3.
Testing	In accordance with the package integrity test method in the relevant annex of <i>ISO 4074</i> .
Requirement	<b>AQL2.5</b>

- 6 As an interim measure pending the production of definitive evidence supporting the benefits of testing oven-conditioned condoms on a LOT-by-LOT basis, it has been decided to make this an optional requirement within the *WHO/UNFPA Specification*. Procuring Agencies may wish to include this requirement in specific contracts depending upon the level of confidence in the supplier.

### Design Requirements

The design properties listed below may be adapted, where appropriately indicated, to reflect the specific needs of the programme and population of intended users. Modification should be based on information about the target population. Verification of compliance with these requirements is to be done as part of the LOT-by-LOT compliance testing of the product.

If specific design changes are agreed between manufacturer and Procuring Agency, then any appropriate testing procedures, sampling plans and compliance levels (AQLs) should also be agreed. Changes in condom design, such as different shapes or the inclusion of pigments, can affect airburst properties and, in some circumstances, freedom from holes.

*It is recommended* that, where changes to the specification are made, dimensional requirements and design features should be subject to *ISO 2859-1* Inspection Level S-2 with an **AQL of 1.0**.

Appropriate reference samples should be maintained by the manufacturer and testing laboratory. The Procuring Agency and/or national regulatory authority may also retain reference samples.

Design Requirements	
shape and texture	
Verify by visual inspection	<p>The surface of the condoms can be textured or non-textured. Texturing typically consists of a number of ribs or dots formed onto the surface of the condom.</p> <p>Condoms may be of any shape consistent with normal commercial practice and client requirements.</p> <p><i>If the condom is not parallel-sided and smooth, attach a dimensioned drawing with detailed description, and check here:</i></p>
Integral bead	
Verify by visual inspection	The open end of the condom shall have a rolled ring of latex, called an integral bead.
Colour	
Verify by visual inspection	<p>Condoms can be translucent or coloured.</p> <p><b>Pigments used with coloured condoms shall be suitable for use in medical devices.</b></p> <p>If a pigment is required, indicate the colour here and provide full details of the pigment, including a Material Safety Data Sheet (MSDS).</p> <div style="border: 1px solid black; width: 100px; height: 15px; margin-left: 400px;"></div>
odour, fragrance and flavor	
Verify by visual inspection and smell	<p>The condoms shall not give off an unpleasant odor when the package is opened at any time after manufacture and for the shelf-life of the product. (Condoms have a characteristic odor of rubber, which tends to dissipate quickly once the package is opened. A mild odor that dissipates quickly is acceptable.)</p> <p>It is suggested that appropriate reference samples be retained by the testing laboratory to help resolve disputes over odor. It is recommended that the retained samples be kept for the duration of the shelf- life of the condom.</p> <p>Procuring Agencies may specify the addition of a suitable fragrance and/or flavour. Such fragrances and flavours must be non-toxic, non-irritant and not degrade the rubber.</p> <p>If a fragrance is desired, describe here (specify fragrance and amount added) and provide full details of the fragrance, including a Material Safety Data Sheet (MSDS).</p>

Design Requirements	
	If a flavour is desired, describe here (specify flavour and amount added) and provide full details of the flavour including a Material Safety Data Sheet (MSDS).
Testing	See Annex III for guidance on odour testing. If a masking agent or flavour is used, odour testing should become part of the LOT-by-LOT Pre-shipment compliance testing. Odour testing should be included in ageing studies.
Width	
Sampling	In accordance with <i>ISO 2859-1</i> Inspection Level S-2.
Testing	In accordance with the test method in the relevant annex of <i>ISO 4074</i> .
Requirement	<p>Standard widths within the public sector are 49 mm and 53 mm, with a tolerance of <math>\pm 2</math> mm.</p> <p><b>AQL 1.0</b></p> <p>Other widths are available and may be more appropriate for specific target populations described in Annex I. Users should select the appropriate width based on the best available data on the target population.</p> <p>Indicate the width here:</p>
Length	
Sampling	In accordance with <i>ISO 2859-1</i> Inspection Level S-2.
Testing	In accordance with the test method in the relevant annex of <i>ISO 4074</i> .
Requirement	<p>A minimum of 165 mm for condoms with widths less than 50.0 mm.</p> <p>A minimum of 180 mm for condoms with widths from 50.0 mm up to 55.5 mm.</p> <p>A minimum of 190 mm for condoms with widths equal to or greater than 56.0 mm.</p> <p><b>AQL 1.0</b></p> <p>Length may be specified based on the best available data on the target population. Indicate the length here:</p> <p>The width is defined as the mean lay-flat width of 13 condoms measured in accordance with the relevant annex of <i>ISO 4074</i> at a point (<math>35 \pm 15</math>) mm from the open end, rounded to the nearest 0.5 mm.</p>
Thickness	
Sampling	In accordance with <i>ISO 2859-1</i> Inspection Level S-2.
Testing	In accordance with the test method in the relevant annex of <i>ISO 4074</i> .
Requirement	<p>The thickness measurements are taken at three points: <math>30 \pm 5</math> mm from the open end, <math>30 \pm 5</math> mm from the closed end (excluding the reservoir tip), and at the mid-distance between those two points.</p> <p>For partially textured condoms the thickness shall be measured at points closest to those specified above where the surface is smooth. The locations of the points of measurement shall be noted.</p> <p>If it is not possible to locate a smooth region on the condom where thickness can be measured, then thickness shall be measured at the points specified above and the specification should be adjusted to allow for the effect of the texturing—for example, by reference to the manufacturer's specification.</p> <p><b>AQL 1.0</b></p> <p>The mean single-wall thickness (calculated from the three individual measurements) for each condom shall be <math>0.065 + 0.015</math> mm – 0.020 mm.</p> <p>Condoms thicker than 0.080 mm are usually considered to be extra thick, whereas condoms that are thinner than 0.060 mm are usually considered to be thin. There is no evidence that extra thick condoms (sometimes called extra strong) provide additional protection.</p>
Design Requirements	
Quantity of lubricant including powder	
Sampling	In accordance with <i>ISO 2859-1</i> Inspection Level S-2.

<b>Testing</b>	In accordance with the test method in the relevant annex of <i>ISO 4074</i> .
<b>Requirement</b>	<p>The condom shall be lubricated with a quantity of silicone fluid having a viscosity between 200 and 350 centistokes.</p> <p><i>Other lubricants such as glycols and water-based lubricants may be used. Oil-based lubricants <b>should NOT</b> be used.</i></p> <p>If an alternative lubricant is required, specify the type here and provide full details of the lubricant including a Material Safety Data Sheet (MSDS).</p> <p>The quantity of lubricant, including powder, in the package should be <math>(550 \pm 150)</math> mg.</p> <p><b>AQL 4.0</b></p> <p><i>If user preferences indicate that it is desirable, lower lubricant levels may be used, but the minimum recommended quantity is 250 mg.</i></p> <p>If the lubricant quantity is less than <math>(550 \pm 150)</math> mg, indicate here:</p>
<b>Individual package materials and markings</b>	
<b>Sampling</b>	In accordance with <i>ISO 2859</i> Inspection Level S-3.
<b>Testing</b>	The sample of condom packages is visually inspected to verify the required aspects of package quality.
<b>Requirement</b>	<p>The colour, print design and identification markings, including Pantone references and font sizes, shall be as specified by the buyer and annexed to this specification.</p> <p>The individual package shall have the following markings:</p> <ul style="list-style-type: none"> <li>• manufacturer's name;</li> <li>• LOT number or LOT identification code (printed at the time of packaging, not pre-printed);</li> <li>• expiry date: month and year labelled expiry date;</li> <li>• date in a language to be specified by the Procuring Agency.</li> </ul> <p><i>Manufacturing date: Month-and-year manufacturing date can be added if required by Procuring Agency.</i></p> <p><b>AQL 2.5</b></p>
<b>Verified by visual inspection</b>	Individual packages shall be square or circular and shall not distort the rolled condom. The package shall be hermetically sealed and shall protect the product from oxygen, ozone, water vapour, ultraviolet light and visible light.
<b>Verified by supplier's data or independent test</b>	The recommended packages should be constructed of a laminate, which includes a layer of suitable impermeable flexible aluminum foil (recommended minimum thickness of 8 micrometers) and layers of plastic materials suitable for the mechanical protection of the metal foil and for printing and sealing.

Design Requirements	
<b>Alternate package materials</b>	<p><i>Alternative package materials can be accepted if they have barrier and strength properties comparable to those of the packaging recommended above or if there are real-time stability data to show that the condom in its pack has adequate shelf-life.</i></p> <p>If an alternative material is required, append the full specification and mark here: The LOT numbers on packages must be printed at the time of packaging.</p> <p>In addition, the following shall apply:</p> <ul style="list-style-type: none"> <li>• There shall be no evidence of leakage.</li> <li>• The outside surface of the package shall be clean.</li> <li>• There shall be no separation of the layers of laminate.</li> <li>• If the sealed packages are in strips, the individual packages are separated by perforations or other means that allow the packages to be separated by hand without interfering with the seals. <input type="checkbox"/></li> <li>• The package must be easy to open without damaging the condom.</li> </ul>

### Packaging for shipment

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

Information included on all packaging shall be in accordance with the language specified by the Procuring Agency.

Packaging Requirements	
<b>consumer packs</b>	<p>A primary pack of 1x10 pieces  Inner Pack (1x10's primary packs)  Master carton (1x72 Inner Packs)</p>
<b>inner boxes</b>	<p>The inner boxes shall be constructed of cardboard. A suitable moisture-resistant barrier on its inner or outer surfaces may be specified by the Procuring Agency. The boxes shall be of sufficient strength and rigidity to retain their shape through every stage of the distribution chain.</p> <p>The inner boxes will be marked in a legible manner to describe the contents and to facilitate identification in case of subsequent query.</p> <p><b>the following information shall be included in the inner box marking:</b></p> <ul style="list-style-type: none"> <li>• LOT identification number;</li> <li>• month and year of manufacture (including the words <i>Date of Manufacture, Month, Year</i>) in language(s) to be specified by the Procuring Agency. The year will be written as a four-digit number and the month as a two-digit number;</li> <li>• month and year of expiry (including the words <i>Expiry Date, Month, Year</i>) in language(s) to be specified by the Procuring Agency. The year will be written as a four-digit number and the month as a two-digit number;</li> <li>• manufacturer's name and registered address;</li> <li>• nominal width of the condom, expressed in millimetres;</li> <li>• number of condoms in box;</li> <li>• instructions for storage.</li> </ul> <p><b>note: All markings must be legible.</b></p> <p>Inner box markings can be specified in accordance with programme requirements.</p>

Packaging Requirements	
Information	<p>If, in accordance with local regulations or programme requirements, information is to be provided with the condom, then the following instructions should be considered for inclusion:</p> <ul style="list-style-type: none"> <li>to handle the condom carefully, including removal from the package so as to avoid damage to the condom by fingernails, jewellery, etc.;</li> <li>how and when to put on the condom; mention should be made that the condom should be placed on the erect penis before any contact occurs between the penis and the partner's body, to assist in the prevention of sexually transmitted infections and pregnancy;</li> <li>to stop and check if the user feels the condom slipping, as it may fall off the penis;</li> <li>to stop and check if the user feels the condom tightening excessively on the penis, as this may lead to breakage;</li> <li>to withdraw the penis soon after ejaculation, while holding the condom firmly in place at the base of the penis;</li> <li>if an additional lubricant is desired, to use the correct type of lubricant, one that is recommended for use with condoms, and the need to avoid the use of oil-based lubricants, such as petroleum jelly, baby oil, body lotions, massage oils, butter, margarine, etc., as these are deleterious to the integrity of the condom;</li> <li>to consult a doctor or pharmacist about the compatibility of topical medicines that might come in contact with the condom;</li> <li>to seek medical assistance as soon as possible within five days, should a condom leak or burst during use;</li> <li>if the individual container is obviously damaged, to discard that condom and use a new one from an undamaged package;</li> <li>instructions on how to dispose of the used condom;</li> <li>a statement that the condom is for single use;</li> <li>the number of the International Standard, i.e. <i>ISO 4074</i>.</li> </ul> <p><b><i>It is recommended that the following statement relating to the safety and effectiveness of the condom be included:</i></b></p> <p><b>“When used correctly every time you have sex, condoms greatly reduce the risk of unintended pregnancy, HIV/AIDs and some other sexually transmitted infections. Use a new condom every time you have sex and follow the instructions carefully.”</b></p>
exterior shipping cartons	<p>The inner boxes shall be packed into plastic or other waterproof lining bags, which will be placed in three-wall cartons made from weather-resistant corrugated fiberboard with a bursting test strength of not less than 1900 kPa.</p> <p>The carton flaps shall be secured with water-resistant adhesive applied to not less than 75% of the area of contact between the flaps, or with 75 mm wide water-resistant tape applied to the full length of the centre seams and extending over the ends by not less than 75 mm.</p> <p>The cartons may be secured by plastic strapping at not less than two positions.</p> <p>Alternatively, wire-bound, cleated plywood or nailed wood boxes are acceptable when lined with a waterproof barrier material.</p> <p>The barrier material must be sealed at the edges with waterproof tape or adhesive, and there must be no sharp protrusions inside the boxes.</p> <p>In some countries the three-wall corrugated fibreboard available is not of sufficient strength and rigidity to meet stacking requirements or to resist being cut at the corners when the plastic strapping is applied. In such cases an inner carton of two-walled corrugated fibreboard shall be inserted into the shipping carton before packing the condoms.</p>

Packaging Requirements	
	<p>The exterior shipping carton, like the inner box, shall be marked with information about the contents in a clearly legible manner. The information shall include:</p> <ul style="list-style-type: none"> <li>• LOT identification number;</li> <li>• month and year of manufacture (including the words <i>Date of Manufacture, Month, Year</i>) in language(s) to be specified by the Procuring Agency. The year shall be written as a four-digit number and the month as a two-digit number;</li> <li>• month and year of expiry (including the words <i>Expiry Date, Month, Year</i>) in language(s) to be specified by the Procuring Agency. The year shall be written as a four-digit number and the month as a two-digit number;</li> <li>• name and address of supplier;</li> <li>• nominal width;</li> <li>• number contained in the carton;</li> <li>• instructions for storage and handling.</li> </ul> <p>To facilitate monitoring of LOT quality during shipping and storage, all exterior shipping cartons for each</p>
<b>lot traceability</b>	<p>Best efforts shall be made to ensure that shipments remain as discrete LOTS and that these LOTS remain intact as far down the distribution system as possible.</p> <p>These efforts may include the use of very large lettering for LOT codes on the exterior shipping cartons; colour coding; using one pallet per LOT; physically linking all exterior shipping cartons from discrete LOTS; and issuing instructions to this effect to shippers and warehouse personnel.</p>

### Summary tables

The following tables summarize the testing methods and requirements for packaging defects, general requirements, performance requirements and design requirements for prequalification and LOT-by-LOT compliance testing.

table 1. Classification of defects in packaging and marking of packaging for delivery	
Examine	Defects
<b>Contents</b>	Number of condoms not as specified; packages or strips not as specified.
<b>Marking</b>	Omitted; incorrect; illegible; of an improper size (exterior, interior), incorrect location, sequences, or method of application.
<b>Materials</b>	Packaging/packing materials not as specified, missing, damaged or non-serviceable.
<b>Workmanship</b>	Shipping cartons inadequately closed and secured; poor application of internal packaging and packing material; distorted intermediate packages.

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

For prequalification testing, UNFPA requires that three lots of condoms be randomly selected for testing. At the time of the prequalification inspection, the inspected factory may not be producing condoms against the *WHO/ UNFPA Male Latex Condom Specification, 2010*. Thus, the manufacturer may not be producing condoms that comply with the full requirements of the *WHO/UNFPA Male Latex Condom Specification, 2010*. This applies in particular to requirements for package marking and labelling, but may apply to other properties such as dimensions. Inspectors and/or inspection companies shall select condom lots for testing that comply as closely as possible with the requirements of the *WHO/UNFPA Male Latex Condom Specification 2010*. The selected sample must comply with and will be tested against the requirements of *ISO 4074: 2002*. UNFPA includes testing condoms that have been oven conditioning for  $(168 \pm 5)$  hours at  $(70 \pm 2)$  °C for bursting pressure and volume during



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

**table 2. summary of prequalification tests and requirements**

<b>sample according to Annex B of ISO 4074 for “isolated Lots” and ISO 2859–1</b>		
<b>Test</b>	<b>sampling</b>	<b>requirements</b>
Verification of constituent materials	NA	Manufacturer’s documentation
Verification of shelf-life	NA	Manufacturer’s documentation
Minimum stability (if required)	As listed below for burst volume, burst pressure, freedom from holes and pack- age integrity	As listed below for burst volume, burst pressure, freedom from holes and package integrity
Bursting volume (before and after oven conditioning)	Level G-I Minimum Code Letter M	Minimum volumes: 1. <b>16.0</b> dm <sup>3</sup> for condoms with widths less than 50 mm 2. <b>18.0</b> dm <sup>3</sup> for condoms with widths from 50 mm to 55.5 mm 3. <b>22</b> dm <sup>3</sup> for condoms with widths greater than 56 mm AQL 1.5
Bursting pressure (before and after oven conditioning)	Level G-I Minimum Code Letter M	Minimum pressure: 1.0 kPa AQL 1.5
Freedom from holes (before and after oven conditioning for $(168 \pm 5)$ h at $(70 \pm 2)$ °C)	Level G-I Minimum Code Letter N	AQL 0.25
Visible defects (before and after oven conditioning for $(168 \pm 5)$ h at $(70 \pm 2)$ °C)	Level G-I Minimum Code Letter N	Critical defects: AQL 0.4 Non-critical defects: AQL 2.5
Shape and texture	Agreed between manufacturer and buyer	Visual inspection
Package integrity (before and after oven conditioning for $(168 \pm 5)$ h at $(70 \pm 2)$ °C)	Level S-3 Minimum Code Letter H	AQL 2.5
Integral bead	Agreed between manufacturer and buyer	Visual inspection
Colour	Agreed between manufacturer and buyer	Visual inspection
Fragrance and flavouring	Agreed between manufacturer and buyer	Sensory inspection
Width	Level S-2	$\pm 2$ mm of claimed width AQL 1.0
Length	Level S-2	1. <b>165</b> mm for widths less than 50 mm 2. <b>180</b> mm for widths between 50 mm and 55.5 mm 3. <b>190</b> mm for widths of 56.0 and above AQL 1.0
Thickness	Level S-2	0.045–0.080 mm AQL 1.0
Lubricant quantity (including powder)	Level S-2	Viscosity: 200–350 centistokes Qty: 400–700 mg/condom AQL 4.0
Odour (if necessary)	Agreed between manufacturer and buyer	Sensory inspection
Inner box	Level S-3	Compliant with procurement specifications
Exterior shipping cartons	Level S-2	Compliant with procurement specifications

**table 3. summary of Lot-by-Lot Pre-shipment compliance testing and requirements**

sample according to Annex A in ISO 4074 for “continuous Lots” and ISO 2859–1		
Test	sampling	requirements
Bursting volume (before and after oven conditioning)	Level G-I	Minimum volumes: 1. <b>16.0</b> dm <sup>3</sup> for condoms with widths less than 50 mm 2. <b>18.0</b> dm <sup>3</sup> for condoms with widths from 50 mm to 55.5 mm 3. <b>22</b> dm <sup>3</sup> for condoms with widths greater than 56 mm AQL 1.5
Bursting pressure (before and after oven conditioning)	Level G-I	Minimum pressure: 1.0 kPa AQL 1.5
Freedom from holes	Level G-I Minimum Code Letter M	AQL 0.25
Visible defects	Level G-I Minimum Code Letter M	Critical defects: AQL 0.4 Non-critical defects: AQL 2.5
Shape and texture	Agreed between manufacturer and buyer	Visual inspection
Package integrity	Level S-3	AQL 2.5
Integral bead	Agreed between manufacturer and buyer	Visual inspection
Colour	Agreed between manufacturer and buyer	Visual inspection
Fragrance and flavouring	Agreed between manufacturer and buyer	Sensory inspection
Width	Level S-2	± 2 mm of claimed width AQL 1.0
Length	Level S-2	1. <b>165</b> mm for widths less than 50 mm 2. <b>180</b> mm for widths between 50 mm and 55.5 mm 3. <b>190</b> mm for widths of 56.0 and above AQL 1.0
Thickness	Level S-2	0.045–0.080mm AQL 1.0
Lubricant quantity (including powder)	Level S-2	Viscosity: 200–350 centistokes Qty: 400–700 mg/condom AQL 4.0
Odour (if necessary)	Agreed between manufacturer and buyer	Sensory inspection
Inner box	Level S-3	Compliant with procurement specifications
Exterior shipping cartons	Level S-2	Compliant with procurement specifications
Individual package materials and markings	Level S-3	Compliant with procurement specifications AQL 2.5

# Technical Specification: TCU380A Intrauterine Device (IUD) <sup>4</sup>

(From WHO draft TCU380A IUD Specification Document May 2010)

*WHO prequalification certification already prevail as mandatory document to be responsive in technical evaluation. The WHO certificate of prequalification will be considered to be the proof of conformity of below mentioned specifications.*

## 1. General Description

The TCU380A IUD consists of a T shaped frame made from low density polyethylene with barium sulphate added for x-ray opacity. The device is 32 mm wide and 36 mm long with a plastic ball at the bottom of the vertical stem to guard against cervical penetration. A small hole may be located on the vertical stem near to its junction with the horizontal arms to act as an anchor for the copper wire. The IUD has solid copper collars on each of its two horizontal arms, each of which has a surface area of 35 mm<sup>2</sup> and copper wire of 310 mm<sup>2</sup> surface area wound tightly around the vertical stem, giving a total surface area of 380 mm<sup>2</sup>, as indicated in the name of the device. A pigmented polyethylene filament is tied in a knot through a small hole in the ball to provide two equal length threads, as a means to locate and remove the device.

The device is supplied sterile in a sealed primary pack together with an insertion instrument consisting of a high-density polyethylene tube and a rod to hold the device correctly positioned within the uterus while the introducer is removed. A moveable plastic flange is positioned on the insertion tube to control the depth of insertion to locate the IUD correctly within the uterus during insertion.

## 2. Materials

The following materials shall be used.

### 2.1 T frame

The T Frame shall be made from low density polyethylene (LDPE) free of stabilizers having a minimum tensile strength of 13 MPa (ASTM D638 – ISO 527–2, using a crosshead speed of 50 mm/min and a type 1 specimen bar) and a 2% secant flexural modulus in the range 133.5 MPa to 180.6 MPa (ASTM D790).

The LDPE shall be blended with 15% to 24% USP precipitated barium sulphate with a particle size of 95% less than 10 micron.

For a specific material, it is only necessary to carry out the assessment of biological safety once. The evaluation shall be repeated if there is a significant change to the materials, for example, if the grade or supplier is changed.

It has been agreed that manufacturers using the original grade of LDPE specified by the Population Council may continue to use this material for a period of two years from the date of publication of this specification before completing this testing.

### 2.2 Copper wire

The wire shall be made from Oxygen Free Electronic (OFE) 99.99% pure copper meeting the National Bureau of Standards designation UNS C10100. The diameter of the wire shall be  $(0.255 \pm 0.005)$  mm (30 AWG<sup>5</sup>, 33 ISWG<sup>6</sup>).

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<sup>4</sup> Evaluation criteria (1) WHO prequalification certificate for international bidders / imported items and Evaluation criteria (2) Batch Inspection certificate from any of the WHO prequalified labs for locally manufactured products

<sup>5</sup> American Wire Gauge

<sup>6</sup> Imperial Standard Wire Gauge

## 2.3 Copper collars

The copper collars shall be made from Oxygen Free Electronic (OFE), 99.99% pure copper meeting the National Bureau of Standards designation UNS C10100<sup>3</sup>. The collars shall be manufactured from copper tube half hard temper with internal diameter ( $1.68 \pm 0.025$ ) mm and external diameter: ( $2.2 \pm 0.025$ ) mm. The collars shall be ( $5 \pm 0.15$ ) mm in length.

The collars shall be deburred, polished and free from sharp edges, for example by barrel tumbling.

## 2.4 Thread

The thread shall be monofilament made from high density polyethylene, (HDPE) free of stabilizers having a sufficient minimum tensile strength to produce a thread meeting the specified strength requirement (9.5 Newton). A material with a minimum tensile strength (ASTM D6380, ISO 527-2) of 28 MPa is recommended.

The thread polymer shall be compounded with 0.4% up to 1.0% by weight of USP (EP) rutile titanium dioxide.

For a specific material, it is only necessary to carry out the assessment of biological safety once. The evaluation shall be repeated if there is a significant change to the materials, for example, if the grade or supplier is changed.

Manufacturers using the original grade of HDPE specified by the Population Council or an equivalent grade that has been used for more than 5 years may continue to use the current material for a period of two years from the date of publication of this specification before completing this testing.

The thread diameter shall be ( $0.25 \pm 0.05$ ) mm. When tested according to ISO 7439: 2002 clause 7 (clamping the thread only) the peak load at break of the thread shall be greater than 9.5 Newton.

## 2.5 Insertion tube

HDPE (High Density Polyethylene) Food Contact grade of internal diameter ( $3.7 \pm 0.1$ ) mm and outside diameter of ( $4.4 \pm 0.1$ ) mm.

## 2.6 Insertion rod

Food contact grade radiation stable ABS (Acrylonitrile-Butadiene-Styrene polymer) or food contact grade radiation stabilized polypropylene (PP) with a tip diameter of ( $2.6 \pm 0.2$ ) mm.

Optionally the insertion rod may be pigmented.

## 2.7 Positioning flange

Polymer with adequate radiation stability to function mechanically post-sterilization. Optionally the flange may be pigmented.

## 2.8 Packaging

Packaging materials shall comply with ISO 11607-1.

Polymer films shall be used, preferably continuous, to reduce the risk of tarnishing the copper.

Tarnishing is a natural phenomenon for copper and does not affect the performance of the IUD. However, significant tarnishing of copper during shelf life may not be aesthetically acceptable. The use of continuous film packaging, where possible, can reduce the risk of tarnishing

### 3. Materials Testing

Every new batch (lot) of compounded frame material (LDPE plus barium sulphate) and thread material (HDPE plus titanium dioxide) as per WHO/UNFPA guidelines.

The barium Sulphate content of the frame material preferably be determined according to ISO 7439: 2002 clause 7.5.

### 4. Materials Storage

The maximum storage period for the frame polymer and the thread is 3 years from the date of manufacture when stored at temperatures under 30 °C and 2 years when stored at temperatures between 30 °C and 35 °C. The maximum storage period for the frame polymer and the thread is 3 years from the date of manufacture when stored at temperatures under 30 °C and 2 years when stored at temperatures between 30 °C and 35 °C.

Provided the tensile strength of the frame material exceeds 13 MPa (which may be determined by testing molded frames) and the breaking force of the thread exceeds 9.5 Newton, then the materials may be used for a further 3 years when stored at temperatures under 30 °C and 2 years when stored at temperatures between 30 °C and 35 °C.

### 5. Materials processing

The recycling of injection molded reclaim material for the T frame and the thread is not permitted.

### 6. Dimensions and Requirements for Finished Product

When tested according to ISO 7439: 2002 clause 7.2, the dimensions of the finished product after sterilization shall comply with the requirements as individually specified below.

- Sampling shall be in accordance with ISO 2859-1, Inspection Level S-4 unless otherwise indicated. Compliance shall be with an AQL of 0.65 unless otherwise indicated.
- Manufactures and testing laboratories may opt to sample in accordance with ISO 3951-1 using the same Inspection level and AQL. In cases of dispute sampling according to ISO 2859-1 shall be used.
- In order to use the tables in ISO 2859-1 it is necessary for the manufacturer to specify the batch (lot) size.
- The manufacturer is responsible for defining the batch size (lot) and ensuring traceability and the use of appropriate sampling in process and product validation.

#### 6.1 T frame dimensions

- Length of horizontal arms (total length of both arms):  $(32 \pm 0.5)$  mm
- Length of vertical stem:  $(36 \pm 0.5)$  mm
- Diameter of horizontal arm:  $(1.6 \pm 0.1)$  mm
- Diameter of vertical stem:  $(1.5 \pm 0.1)$  mm

Optionally a hole for anchoring an end of the copper wire may be provided. The hole must not reduce the breaking strength of the vertical stem that is specified below in Performance Requirements 7.4.

#### 6.3 Breaking strength

The hole may be tapered or dumbbell shaped with a maximum diameter: 0.55 mm and placed  $(2.8 \pm 0.14)$  mm from the intersection of the horizontal arm and vertical stem centerlines.

T Piece Ball (at end of vertical stem) diameter:  $(3.0 \text{ mm} \pm 0.7 \text{ mm})$ . The junction between

the ball and the vertical stem shall preferably be radiused.

T Piece Ball (at end of vertical stem) shall have a hole of maximum diameter 0.79 mm for securing the thread. The hole may be tapered or dumbbell shaped.

The junctions between the horizontal arms and the vertical stem may be radiused to prevent stress concentrations. If the junction is radiused the radius shall be between 0.25 - 0.40 mm. Manufacturers shall confirm that introducing the radius does not lead to an increase in crush damage at the junction when the T is deformed as it is loaded into the insertion tube. This can be done by comparing the strength of radiused and non radiused T frames after loading in the insertion tube. Microscopic examination should be used alongside strength testing to monitor the extent of any damage.

### 6.3 Thread dimension

Sampling shall be in accordance with ISO 2859-1, Inspection Level S-4. Manufactures and testing laboratories may opt to sample in accordance with ISO 3951-1 using the same Inspection level and AQL. In cases of dispute sampling according to ISO 2859-1 shall be used.

- Compliance shall be with an AQL 1.5 for thread length.
- Thread Length: The length of each tail shall be 105 to 125 mm.

### 6.4 Copper collars

- Collar length:  $(5.0 \pm 0.15)$  mm
- Collar weight:  $(68.7 \pm 3.0)$  mg
- Collar Position:  $5.4 \pm 0.4$  mm from the ends of the T horizontal arm.

### 6.5 Copper wire

The weight of wire on the frame shall be not less than 165 mg and not more than 187 mg.

### 6.6 Insertion tube

Length:  $(206 \pm 2)$  mm

Internal Diameter:  $(3.7 \pm 0.1)$  mm Outside Diameter:  $(4.4 \pm 0.1)$  mm

### 6.7 Insertion rod

Length:  $(190 \pm 5)$  mm from handle brace to tip. Diameter at tip:  $(2.6 \pm 0.2)$  mm

### 6.8 Insertion tube flange

Sampling shall be in accordance with ISO 2859-1, Inspection Level S-4. Manufactures and testing laboratories may opt to sample in accordance with ISO 3951-1 using the same Inspection level and AQL. In cases of dispute, sampling according to ISO 2859-1 shall be used.

Compliance shall be with an AQL of 1.5. Diameter of central hole:  $(4.1 \pm 0.1)$  mm

The shape and dimensions of the central hole may be changed to facilitate meeting the specified flange displacement force.

### 6.9 Other assist components

These are other optional components which the manufacturer may evaluate and choose to include. When considering design and choice of materials for these components, manufacturers shall take into account the function of the devices, the type and duration of exposure to the body and the effect of sterilization by gamma radiation.

## 7. Performance Requirements

### 7.1 Copper surface area

The total nominal active copper surface area, wire and collars shall be  $380 \text{ mm}^2 \pm 10\%$ .

### 7.2 Copper wire winding

The wire shall be wound so that it is in contact with the frame and is uniform. The proximal and distal end of the wire must lie smoothly on the T surface and not protrude beyond the wire profile to prevent any chance abrasion of uterine tissue during insertion or in situ. The length of wire protruding from the anchoring hole ('the tag') shall not exceed 10mm. It shall be bent down to run parallel with the vertical stem and not interfere with the position of the arms when the IUD is placed in the insertion device.

Single and double wound configurations are acceptable.

### 7.3 Thread knot

The knot shall be secure and not promote breakage under normal use.

### 7.4 Breaking strength

Sampling shall be in accordance with ISO 2859-1, Inspection Level G I. Manufactures and testing laboratories may opt to sample in accordance with ISO 3951-1 using the same Inspection level and AQL. In cases of dispute, sampling according to ISO 2859-1 shall be used.

Compliance shall be with an AQL of 1.0.

When pulled at 200 mm/minute, according to ISO 7439: 2002 clause 7.3 with the arms bent upwards and clamped parallel ( $8 \pm 2$ ) mm and a single thread clamped, the breaking force of the finished product after sterilization shall be greater than 9.5 Newton.

Temperature during testing shall be  $23 \pm 2^\circ\text{C}$ .

Conditioning as specified in ISO 7439: 2002 needs to be carried out only in the case of disputes.

When conducting the tensile test, the T frame shall be clamped by the copper collars (only) on the horizontal arms, using a gripping fixture that deforms the arms simultaneously parallel to each other and to the vertical stem, with horizontal arms ( $8 \pm 2$ ) mm apart, centre-line to centre-line. The tee junction must be unconstrained by the clamp.

In use, the toggle clamp should be sufficiently tightened to prevent slippage but not so tight that it fully crushes the collars.

One of the threads shall be gripped in the opposing grip at a distance of 5 cm from its point of attachment to the IUD. A grip with parallel flat rubber faces has been found satisfactory if well-tightened. Force is then applied and the IUD is stretched until either it or the thread breaks or detaches. The force at break or detachment is measured and recorded. Any tensile test should be rejected if breakage of the thread occurs at the entry to the grip.

The location of failure for any device failing the minimum strength requirement shall be noted (thread, thread/ball junction, wire insertion hole in vertical stem, or the junction between the vertical and horizontal arms).

### 7.5. Flexibility test

Sampling shall be in accordance with ISO 2859-1, Special Inspection Level S-4.

Manufactures and testing laboratories may opt to sample in accordance with ISO 3951-1 using the same Inspection level and AQL. In cases of dispute sampling according to ISO 2859-1 shall be used.

Compliance shall be with an AQL of 4.0.

When a 20g weight is applied to one of the horizontal arms of the T frame for a period of 20 seconds at a distance 12 mm from the vertical arm, the deflection of the horizontal arm measured at the end of the arm shall be as follows:

For freshly manufactured T frames that are greater than 24 hours but less than 96 hours from time of molding: within the range 4.8 mm to 6.5 mm.

For T frames that are older than 96 hours: greater than 4.0 mm.

The test shall be carried out at a temperature of  $(23 \pm 2) ^\circ\text{C}$ . Before testing the T frames shall be stored for at least 6 hours at the test temperature.

A suitable test rig may be used to clamp the T frame and measure the amplitude of the deflection. A pivoted needle or lever may be used to amplify the deflection of the horizontal arm Flexibility Apparatus. If such a test rig is used the T frame arm deflection may be converted into a scale reading using the appropriate amplification factor for the rig.

#### 7.6 Copper collar retention force

Sampling shall be in accordance with ISO 2859-1, Inspection Level S-4. Manufactures and testing laboratories may opt to sample in accordance with ISO 3951-1, using the same Inspection level and AQL. In cases of dispute sampling according to ISO 2859-1 shall be used.

Compliance shall be with an AQL of 4.0.

The minimum force required to displace a collar on the arm shall be 6.86 Newton (700 g -force).

When conducting the copper collar retention force, test the T frame shall be clamped by the collar on one of the arms using a suitable jig if necessary and the opposing arm shall be gripped in the opposite clamp.

Optionally one collar may be clamped in one jaw and the other collar clamped in the opposing jaw. The clamp(s) gripping the copper collar shall have a groove milled with a 1.59 mm (1/16 inch) ball end mill to a depth of 1.38 mm, or about 65% of the collar diameter, to prevent crushing the collar.

#### 7.7 Memory

When the finished product after sterilization is tested according to ISO 7439: 2002 clause 7.4, the maximum displacement from the horizontal of the horizontal arms shall be not greater than 5.0 mm.

Sampling shall be 20 units per lot irrespective of lot size.

#### 7.8 Insertion instrument

The insertion rod shall be a snug fit but slide smoothly within the insertion tube and shall not trap the thread.

#### 7.9 Flange displacement force

Sampling shall be in accordance with ISO 2859-1, Inspection Level S-4. Manufactures and testing laboratories may opt to sample in accordance with ISO 3951-1 using the same



Inspection level and AQL. In cases of dispute, sampling according to ISO 2859-1 shall be used.

Compliance shall be with an AQL of 0.65.

Use a steadily applied displacement. The required force should fall between 2.0 and 9.0 Newton.

## 8. Packaging

- Packaging shall comply with ISO 11607 Part 1.
- Continuous polymer films shall be used to reduce the risk of tarnishing unless ethylene oxide is used for sterilization.
- Continuous polymer films cannot be used with ethylene oxide sterilization. A suitable Ethylene Oxide permeable microbiological barrier shall be used in accordance with ISO 11607 Part 1.

### 8.1 Sealed pouch

IUDs shall be packed in individual sealed pouches.

### 8.2 Sealed pouch integrity

Sampling shall be in accordance with ISO 2859-1, Inspection Level S-4.

Compliance shall be an AQL of 0.65.

Sealed pouch integrity shall be tested according to ASTM D3078 (Standard test method for determination of leaks in flexible packaging by bubble emission).

If permeable packaging material is used, sealed pouch integrity shall be tested by ASTM F 1929 (Standard test method for detecting seal leaks in porous medical packaging by dye penetration).

### 8.3 Sealed pouch peel strength

Sampling shall be in accordance with ISO 2859-1, Inspection Level S-4. Manufacturers and testing laboratories may opt to sample in accordance with ISO 3951-1, using the same Inspection level and AQL. In cases of dispute sampling according to ISO 2859-1 shall be used.

Compliance shall be with an AQL of 0.65

When tested according to ASTM F 88 (standard test method for seal strength of flexible barrier materials) the peel force shall be not less than 4.4 N/2.54 cm and not greater than 19 N/2.54 cm.

- If the packaging is made from two equally flexible materials Technique B of ASTM F 88 shall be used (sample supported at 90° by hand).
- If a rigid material is used as part of the pack, for example a molded tray then Technique C of ASTM F 88 shall be used (sample supported at 180°).

### 8.4 Labeling and inserts

Information required in accordance with ISO 7439 including information intended for the women shall be provided in accordance with the contractual requirements agreed with the Procuring Agency. Up-to-date information on IUDs can be obtained from WHO publications already referenced in this document.

The following information shall be supplied:

- The Latest Insertion Date (LID) is the date after which the product cannot be inserted in utero.
- The Latest Insertion Date shall be printed on the sealed pouch and shall be based on the maximum product shelf life from the date of sterilization.

The sterilization shall be completed within 30 days of sealing the finished device in the pouch. In addition, the duration of the maximum period the device can remain in utero shall be printed on the primary container. This period shall not exceed 12 years from the date of insertion.

## 8.5 Printing

All printing shall be clear and readily legible.

## 8.6 Cleanliness

The device, insertion tube, insertion rod, flange and any insert such as instructions included in the pack shall be free of visible particulate matter.

# 9. Sterility

## 9.1 Sterilization method

Sterilization shall be by radiation according to ISO 11137 series or by Ethylene Oxide according to ISO 11135 series and standards normatively referenced therein. Radiation sterilization is preferred to allow the use of continuous polymer film packaging materials.

## 9.2 Sterility assurance level

The sterilization assurance level shall be  $10^{-6}$ .

## 9.3 Residual Ethylene Oxide levels

If ethylene oxide sterilization is used, then residual ethylene oxide levels shall not exceed 10 ppm and ethylene chlorohydrin levels shall not exceed 20 ppm on any individual sample when measured using a method that complies with the requirements of ISO 10993-7.

Average residual levels across all samples tested shall not exceed 5 ppm for ethylene oxide and 10 ppm for ethylene chlorohydrin.

# 10. Latest insertion date (LID)

The maximum permitted shelf life for storage of the device prior to insertion is 5 years and this defines the 'Latest Insertion Date' (LID).

A two year transition period from the date of publication of the specification to implement this requirement has been agreed with the manufacturers.

Shelf life claims shall be supported by appropriate stability data.

Guidance on conducting stability studies is given in Annex 5 - Accelerated Ageing Testing. When conducting stability studies, manufacturers shall include products assembled from components that have been stored for the maximum component storage periods, specified by the manufacturer.

# 11. Materials Procurement - Good Manufacturing Practice (GMP)

Manufacturers shall take appropriate steps to ensure that batches of compounded materials (T and thread materials) are not contaminated by any extraneous impurities during compounding operations.

Where lubricants are used in molding, the grades shall be 'Food Grade' and/ or suitable for medical device manufacture. Manufacturers shall introduce procedures to monitor and control the

degree of tarnish and rough edges on the copper component. If appropriate the copper components should be cleaned prior to assembly.

## 12. Dimensional Tolerances and Manufacturing Tolerance Specifications

The nominal specified dimensions and tolerances may not provide the correct clearance for components such as the insertion rod which must slide smoothly and the flange which has to have the correct displacement force. It remains the responsibility of the manufacturer to produce a fully functioning, safe and effective product within the dimensional tolerance limits provided.

## 13. Workmanship

Finished IUDs should be inspected visually for evidence of visible defects and poor workmanship. Defects are divided into two categories depending upon the level of impact they may have on the safety, effectiveness and acceptability of the product. Defects that might be expected to affect the safety and or effectiveness of the product are classified as critical defects and an AQL of 0.65 is applied. Defects that might affect the acceptability of the product, causing the device to be rejected at the time of insertion, are classified as minor defects and an AQL of 2.5 applies. Manufacturers and testing laboratories should maintain a list of these defects with clear definitions and diagrams or photographs to assist both in the assessment of workmanship and in the resolution of any disputes.

## 14. Critical Visible defects

0.65 AQL - assessed by visual examination not measurement

- a) Tarnishing
- b) Missing components
- c) Flash on the mould lines of the T Frame
- d) Sharp protruding edges and burrs
- e) Unsecured thread
- f) Incomplete/deformed ball
- g) Deformed collars
- h) Improperly sealed pouches
- i) Empty pouches
- j) Embedded/surface/foreign particles

## Non-critical visible defects

2.5 AQL- all assessed by visual examination not measurement

- a) Insertion rod bent or distorted
- b) Discoloration of plungers
- c) Damaged packing cartons - depending on severity

## 15. Certificate of Registration Status in Country of Origin

IUDs offered under this purchase description shall be licensed for marketing by the drug regulatory authority of the country of origin. Prior to award of the Contract, the successful offeror(s) may be required to submit a "statement of licensing status of pharmaceutical products(s)" as provided under the World Health Organization (WHO) Certification Scheme, if applicable.

## 16. Compliance with Good Manufacturing Practices

The Supplier must be able to provide certification that the IUDs are manufactured according to

WHO good manufacturing practices (GMP). Supplier also must be able to provide copies of its annual GMP audit reports.

## 17. Quality Assurance Provisions

### 17.1 Compliance

The Supplier shall guarantee that the products as packed for shipment comply with all provisions of the specification and related documents.

### 17.2 Documentation

The Supplier shall provide evidence of the satisfaction of the technical specification requirements for which specific inspection instructions or protocols have not been provided. Such evidence is contained in the “Manufacturer’s Batch Certificate” under the WHO Certification Scheme.

The Supplier shall provide a copy of the manufacturing record and procedures to the Procuring Agency for each lot intended for shipment.

The Supplier shall provide a copy of the Certificate of Analysis to the Procuring Agency for each lot intended for shipment.

The Supplier shall provide to the Procuring Agency a copy of the approval of each component for each lot intended for shipment.

### 17.3 Inspection by the Procuring Agency

The Procuring Agency reserves the right to perform or cause to be performed any of the inspections and tests set forth in the Specification and Special Conditions of Contract to ensure that the contraceptives conform to prescribed requirements. The Procuring Agency reserves the right, and/or may assign the right to a representative, to enter and inspect the production facility prior to supply of the contraceptives and to draw samples from the Supplier’s factory and/ or warehouse. Except as otherwise specified in the contract or purchase order, prior to shipment the Procuring Agency will sample or cause to be sampled the product as packed in inner boxes preparatory to packing in exterior shipping cartons. The sampling shall be according to recognized standards.

The Procuring Agency may have some or all of the tests specified in the contract performed by a laboratory suitably equipped and qualified to conduct quality assurance tests on IUDs.

### 17.4 Sampling Procedures

The Procuring Agency or the Procuring Agency’s representative shall select the required samples from the lot according to the Technical specification of the Special Conditions of Contract. If the order is to be filled using more than one production lot, each production lot shall be separately sampled and tested.

Where an inspection lot is smaller than 10,001 units, it will be deemed to be 10,001 for determination of sample sizes. The normal, tightened, and reduced inspection provisions of ISO 2859 (Inspec).

## Technical Specification: Sub-dermal Implants<sup>7</sup>

*WHO prequalification certification already prevail as mandatory document to be responsive in technical evaluation. The WHO certificate of prequalification will be considered to be the proof of conformity of below mentioned specifications.*

### General Description

Hormonal implants are small flexible matchstick-sized rods which release progestin when inserted under the skin of the upper arm to prevent pregnancy. Contraceptive Implants are effective for 3 to 5 years, depending on the type and are immediately reversible. First introduced in the mid-1980s as Norplant, a six-capsule product, newer generations of products are smaller, require less time to insert and remove, and produce fewer bleeding disturbances for users.

Types of implants:

- A two-rod product contains levonorgestrel a progestin and offers contraception for up to five years.
- A single-rod system that contains etonogestrel a progestin and provides contraception for three years.

### Materials

The two rods Levonorgestrel implants are a progestin-only product; they contain no estrogen. A set consists of two small, flexible rods that have a core consisting of an equal mixture of levonorgestrel and silicone elastomer. The rods are covered with thin-walled silicone tubing and are sealed at the ends with Silastic medical grade adhesive. Each rod is 43 millimeters (mm) long, 2.5 mm in diameter and contains 75 mg Levonorgestrel (LNG).

The single sterile rod implant is 4 cm in length with a diameter of 2 mm. **It** consists of an ethylene vinyl acetate (EVA) copolymer core, containing 68 mg of the synthetic progestin etonogestrel (ENG), surrounded by an EVA copolymer skin. The applicator consists of acrylonitrile-butadiene styrene body with a stainless steel needle and a polypropylene shield.

### Packaging

The two rod implant is supplied as a set. One sealed, sterile plastic pouch contains two rods, each filled with 75 mg of levonorgestrel, for use in one woman.

The single rod implant containing 68mg etonogestrel is preloaded in the needle of a disposable applicator. The sterile applicator containing implant is packed in a blister pack.

- Packaging shall comply with ISO 11607 Part 1.
- Continuous polymer films shall be used to reduce the risk of tarnishing unless ethylene oxide is used for sterilization.
- Continuous polymer films cannot be used with ethylene oxide sterilization. A suitable Ethylene Oxide permeable microbiological barrier shall be used in accordance with ISO 11607 Part 1.

Sealed pouch

Implants shall be packed in individual sealed pouches.

Sealed pouch integrity

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<sup>7</sup> Evaluation criteria (1) WHO prequalification certificate for international bidders / imported items and Evaluation criteria (2) Batch Inspection certificate from any of the WHO prequalified labs for locally manufactured products

Sampling shall be in accordance with ISO 2859-1, Inspection Level S-4.

Sealed pouch integrity shall be tested according to ASTM F2096 (Standard test method for determination of leaks in flexible packaging by bubble emission).

#### Package Impurities

The package material evaluation should meet requirements for the package impurities test specifications of 'USP 661 Containers: Physicochemical tests- plastics'.

#### Sealed pouch peel strength

Sampling shall be in accordance with ISO 2859-1, Inspection Level S-4. Manufactures and testing laboratories may opt to sample in accordance with ISO 3951-1, using the same Inspection level and AQL. In cases of dispute sampling according to ISO 2859-1 shall be used.

Compliance shall be with an AQL of 0.65

When tested according to ASTM F 88 (standard test method for seal strength of flexible barrier materials) the peel force shall be not less than 4.4 N/2.54 cm and not greater than 19 N/2.54 cm.

- If the packaging is made from two equally flexible materials Technique B of ASTM F 88 shall be used (sample supported at 90° by hand).
- If a rigid material is used as part of the pack, for example a molded tray then Technique C of ASTM F 88 shall be used (sample supported at 180°).

#### Labeling and inserts

Information required in accordance with ISO 7439 including information intended for the women shall be provided in accordance with the contractual requirements agreed with the Procuring Agency.

The following information shall be supplied:

- The Latest Insertion Date (LID) is the date after which the product cannot be inserted.
- The Latest Insertion Date shall be printed on the sealed pouch and shall be based on the maximum product shelf life from the date of sterilization.

#### Printing

All printing shall be clear and readily legible.

#### Sterility

##### Sterilization method

Sterilization shall be by Ethylene Oxide according to ISO 11135 series and standards normatively referenced therein.

##### 9.2 Sterility assurance level

The sterilization assurance level shall be 10<sup>-6</sup>.

##### 9.3 Residual Ethylene Oxide levels

Standard ISO-10993-7: Ethylene Oxide Residuals

#### Storage and shelf life

The sterile packs of **two** rods Levonorgestrel implant should be stored away from excessive heat (temperatures higher than 30°C) and moisture. An unopened, undamaged sterile pack of

**two** rods, if properly stored, has a shelf life of 3 to 5 years. The last date for insertion (expiration date) is stamped on each box.

Store etonogestrel implant at 25°C (77°F); excursions permitted to 15°-30°C (59°-86°F). Protect from light. Avoid storing in direct sunlight or at temperatures above 30°C (86°F).

Shelf life claims shall be supported by appropriate stability data.

Guidance on conducting stability studies is given in Annex 5 - Accelerated Ageing Testing. When conducting stability studies, manufacturers shall include products assembled from components that have been stored for the maximum component storage periods, specified by the manufacturer.

### **Effective life**

If inserted anytime before the expiration date (shelf life), a set of **two** rods is effective for 5 years. The rods should be removed by the end of the fifth year. If desired, a new set of rods may be inserted in the same location immediately following removal.

### **Certificate of Registration Status in Country of Origin**

Implants offered under this purchase description shall be licensed for marketing by the drug regulatory authority of the country of origin. Prior to award of the Contract, the successful offeror(s) may be required to submit a “statement of licensing status of pharmaceutical products(s)” as provided under the World Health Organization (WHO) Certification Scheme, if applicable.

### **Compliance with Good Manufacturing Practices**

The Supplier must be able to provide certification that the Implants are manufactured according to WHO good manufacturing practices (GMP). Supplier also must be able to provide copies of its annual GMP audit reports.

### **Quality Assurance Provisions**

#### **Compliance**

The Supplier shall guarantee that the products as packed for shipment comply with all provisions of the specification and related documents.

#### **Documentation**

The Supplier shall provide evidence of the satisfaction of the technical specification requirements for which specific inspection instructions or protocols have not been provided. Such evidence is contained in the “Manufacturer’s Batch Certificate” under the WHO Certification Scheme.

- Verification that each lot meets the requirements specified by the regulatory authority.
- Specifications for Active Ingredient content
- Evaluation of residuals remaining after the sterilization process
- Evaluation of levels of metal elements (Based on USP <231>USP General Chapter on Inorganic Impurities: Heavy Metals)
- Evaluation of residual levels of solvents utilized during the manufacturing process (Standard: Based on USP <467> Organic Volatile Impurities)
- Tests to evaluate the presence of bacterial endotoxins and evaluate biological reactivity
- Tests to predict how the body will react to product contact

- Tests to ensure that the package is sealed appropriately
- Tests to show that the package can be used in contact with the product

The Supplier shall provide a copy of the manufacturing record and procedures to the Procuring Agency for each lot intended for shipment.

The Supplier shall provide a copy of the Certificate of Analysis to the Procuring Agency for each lot intended for shipment.

The Supplier shall provide to the Procuring Agency a copy of the approval of each component for each lot intended for shipment.

#### Inspection by the Procuring Agency

The Procuring Agency reserves the right to perform or cause to be performed any of the inspections and tests set forth in the Specification and Special Conditions of Contract to ensure that the contraceptives conform to prescribed requirements. The Procuring Agency reserves the right, and/or may assign the right to a representative, to enter and inspect the production facility prior to supply of the contraceptives and to draw samples from the Supplier's factory and/ or warehouse. Except as otherwise specified in the contract or purchase order, prior to shipment the Procuring Agency will sample or cause to be sampled the product as packed in inner boxes preparatory to packing in exterior shipping cartons. The sampling shall be according to recognized standards.

The Procuring Agency may have some or all of the tests specified in the contract performed by a laboratory suitably equipped and qualified to conduct quality assurance tests on Implants.

#### Sampling Procedures

The Procuring Agency or the Procuring Agency's representative shall select the required samples from the lot according to the Technical specification of the Special Conditions of Contract. If the order is to be filled using more than one production lot, each production lot shall be separately sampled and tested.

Where an inspection lot is smaller than 10,001 units, it will be deemed to be 10,001 for determination of sample sizes. The normal, tightened, and reduced inspection provisions of ISO 2859 (Inspec).

#### Inspection Sampling and Testing

WHO prequalification certification already prevail as mandatory document be responsive in technical evaluation. The WHO certificate of prequalification will be considered to be the proof of conformity of mentioned specifications. (applicable for imported items only).



# Evaluation Forms

Evaluation Criteria for Manufacturer / Importers of Contraceptives i.e. Condoms, IUCD and Implants																				
S. No.	Product General Parameter				Technical Evaluation Matrix															Suppliers Technical Score
					Principal's and Importers Evaluation Parameters															
					Principal Manufacturer Evaluation								Importer's Evaluation							
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	
					Submission of audited balance sheets along with Income Tax Returns for up to last 3 years. Maximum Marks for this criterion is 4, • Documents submitted for last 3 years = 4 Marks , 2 years = 3 marks , 1 year = 2 mark and no documents = 0 marks	Annual turnover/sales value of the manufacturer should be at least USD 2 million / year. During the last 3 years (three years) Maximum Marks for this criterion is 3, • Documents showing average sales turnover of quoted item as USD. 2 Million / year for last 3 years= 3 marks	Valid Proof of export by the Principal Manufacturer to US/Europe/SRA country/ies, not older than one year. 02 mark each for export to US, 02 mark each for export to Europe & 02 mark for export to SRA Country/ies.	Valid Proof of manufacturing unit production capacity i.e. 4 times of the total demand of the Procurement= 3 marks & 8 times of the total demand of the Procurement= 6 marks	Valid ISO 14001 certificate issued by authorized body of the country of origin duly accredited with International Accreditation Forum (IAF) for the country of origin (duly attested by senior executive of the firm).	Valid ISO 9001 certificate issued by authorized body of the country of origin duly accredited with International Accreditation Forum (IAF) for the country of origin (duly attested by senior executive of the firm).	Valid ISO 13485 certificate issued by authorized body of the country of origin duly accredited with International Accreditation Forum (IAF) for the country of origin (duly attested by senior executive of the firm).	Valid calibration certificate for equipment in the factory.	ISO 10993 certificate issued by the relevant certification body from the country of origin as authorized by the IAF for the said purpose in the name of principal manufacturer.	Submission of audited balance sheets along with Income Tax Returns for up to last 3 years. Maximum Marks for this criterion is 3, • Documents submitted for last 3 years = 3 Marks , 2years = 2 marks , 1 year = 1 mark and no documents = 0 marks	Annual turnover/sales value of the manufacturer should be at least USD 2 million / year. during the last 3 years (three years)Maximum Marks for this criterion is 3, • Documents showing average sales turnover of quoted item as USD. 2 Million / year for last 3 years= 3 marks , 2 years = 2 marks , 1 year = 1 mark and less than the above = 0 marks.	Valid ISO 9001 certificate issued by authorized body of the country of origin duly accredited with Pakistan National accreditation council ( PNAC) for the country of origin (duly attested by senior executive of the firm).	Adherence to Good storage practices (GSP) for finished good storage of the quoted item/s. Subject to physical inspection of technical expert/s by designated committee.	Adequate availability of qualified & relevant Human Resource (Certified by the senior executive of the firm & evaluated by MCC expert/s at the time of inspection).		
	Ref. No. of item	Generic Name of Item	Trade Name	Size, Gauge, etc. of Device	4	3	6	6	4	4	4	4	6	3	3	2	4	4	57	

Note: All the documents / certificates submitted by the concerned shall be attested by the senior executive of the firm.

Evaluation Criteria for Manufacturer / Importers of Contraceptives i.e. Condoms, IUCD and Implants							
Technical Evaluation Matrix							
Product Technical Evaluation		Total Technical Score	Financial Evaluation				Final Grand Total of Scores
18	19	20	21	22	23	24	25
Stability Data (Real & Accelerated where required) of the quoted item/s.	CEJIS/US FDA certification of the quoted products, 3 mark for each certification, up to a maximum of 09 marks		Quoted Unit Price	Lowest Quoted Unit Price among the qualified bids for particular item	Maximum Allocable Unit Price Score	Score awarded to the unit price of quoted item	
4	9	70			30		100

**PART TWO**  
**SECTION - VI**  
**BID FORMS**

## **BID FORM-1**

### **BID COVER SHEET**

#### **Mandatory General Information of Applicant Firm**

**NOTE: Complete filling of this form along with the provision of all requisite information is mandatory. Missing or not providing any of the requisite information may lead to disqualification of the bidder/s from the bidding competition without any correspondence. Any appeal from bidder/s, for whatsoever reasons, shall not be entertained in such a case.**

S. No.	Name of the Bidding Firm:	
1.	Please indicate whether the firm is: i. Manufacturer, or ii. Importer, or iii. Both; Manufacturer as well as Importer For various items offered for this bidding competition.	
2.	Please indicate out of the following category/ies, under which the Firm is applying for bidding: i. General medicines (contraceptives, oral pills) ii. Injectables (Contraceptives) iii. Medical devices including IUCD, Implants iv. Non drug items (NDIs) Male Latex Condoms.	
3.	<p>Please provide names, attested copies of CNICs, two recent attested photographs, valid street addresses in Pakistan, all working landline, mobile phone numbers and valid email address of the following:</p> <p>i. Owner/Proprietor of the Firm; and ii. Managing Director / CEO of the Firm; and iii. Focal person officially made responsible and authorized by the Firm for day to day official correspondence/communication with the procuring agency related in relation to this bidding competition.</p> <p><b>Note:</b> 1. In case of winning this bidding competition the Focal person of the successful bidder shall be responsible for communication with purchasing agency/ies regarding supply related issues and his valid contact No. and address may be given in final approved rate list for facilitation of purchasing agency/ies. 2. Please provide clear, legible and visible attested photocopies of all the valid requisite items mentioned items)</p>	
4.	<p>Please provide the following valid information regarding applicant Firm and/or authorized agent, where applicable</p> <p>i. Complete street address of the: a. Head Office b. Main warehouse; and ii. Valid &amp; working official Landline Phone and Fax Numbers; and</p>	

	<ul style="list-style-type: none"> <li>iii. Valid Mobile phone number/s of the Focal Person registered which should be registered on his/her CNIC No. and name; and</li> <li>iv. Valid and functional Email address; and</li> <li>v. Official Website address/es.</li> </ul>	
<b>5.</b>	<p>Please provide, in original, the bids security instrument amounting 2% of the total bid value along with the Financial Proposal in the sealed envelope in the form of valid, crossed Call Deposit Receipt / Bank Draft from a scheduled Bank of Pakistan in the name of Project Director Integrated Health Project, Khyber Pakhtunkhwa, Peshawar. Any ordinary bank account cheques/s shall not be acceptable as bids security.</p> <p><b>Note:</b> Please also provide an attested photocopy of the same bids security document in the sealed envelope of technical Proposal.</p>	
<b>6.</b>	<p>Please provide attested copies of the following Tax related valid documents:</p> <ul style="list-style-type: none"> <li>i. National Tax Number (NTN) of the Firm for Income Tax, and</li> <li>ii. Last year Income Tax Return of the Firm; and</li> <li>iii. Sale Tax Registration Certificate of the Firm; and</li> <li>iv. Certificate of Professional Tax of the Firm.</li> <li>v. Audited Balance Sheet along with Income Tax Return for up to last three years as required under Technical Evaluation Criteria</li> <li>vi. Annual turnover/Sales Value as required under Technical Evaluation Criteria</li> </ul>	
<b>7.</b>	<p>In case of being a Manufacturer, the Firm should provide attested copies of the following documents also:</p> <ul style="list-style-type: none"> <li>i. Valid Drugs Manufacturing License issued by the Drugs Regulatory Authority of Pakistan (DRAP); and</li> <li>ii. Valid Product Registration Certificate issued by the DRAP for the item/s quoted by the Firm or <b>even if the firm has applied for the registration of the quoted item to DRAP could also be considered but subject to provision of valid proof.</b></li> <li>iii. Valid cGMP certificate issued by DRAP <b>even if the firm has applied for the renewal of cGMP of the quoted item to DRAP could also be considered but subject to provision of valid proof.</b></li> <li>iv. Valid Price List of the quoted item/s</li> </ul>	

8.	<p>In case of being Importers, the Firm should provide attested copies of the following documents also:</p> <ul style="list-style-type: none"> <li>i. Valid Drugs Sales License for the importer <b>from the relevant authority of area of jurisdiction</b>; and</li> <li>ii. Valid Product Registration Certificate issued by the DRAP for the imported item/s quoted by the Firm or <b>if the firm has applied for the imported item/s registration to DRAP, shall provide valid proof and could be considered as the case may be; and</b></li> <li>iii. Valid Agency Agreement with the Foreign Principal Manufacturer entity/ies; and</li> <li>iv. <b>Valid cGMP Certificate/quality control certificate/ quality assurance certificate/ Medical Device management certificate of the Principal Manufacturer for the quoted item/s as issued by relevant authority of the country of origin of the quoted imported good/s (duly attested from the Notary public (as the case may be) of the country of origin shall be verified via email from principal manufacturer and the principal manufacturer shall be bound to reply within 14 days. Non provision of this document shall lead to disqualification of the firm; and</b></li> <li>v. <b>Valid Free Sale Certificate for the quoted item/s as issued by relevant authority of the country of origin of the quoted imported good/s issued by relevant authority of the country of origin of the quoted imported good/s (duly attested from the Notary public (as the case may be) of the country of origin shall be verified via email from principal manufacturer and the principal manufacturer shall be bound to reply within 14 days. Non provision of this document shall lead to disqualification of the firm; and</b></li> <li>vi. Valid Price List of the quoted items if applicable.</li> <li>vii. <b>“Nationality”</b> as required under 1.1 of Technical Evaluation Criteria</li> <li>viii. <b>“Conflict of Interest”</b> as per rules.</li> <li>ix. <b>“Not Declared Ineligible”</b> as required under Technical Evaluation Criteria</li> <li>x. <b>“WHO Prequalification certificate (For Condoms, IUCDs and Implants)</b> as required under Technical Evaluation Criteria</li> <li>xi. <b>Undertaking</b> regarding “Lab Testing of Locally Manufactured Contraceptives” as required under Technical Evaluation Criteria –Required Document is an Affidavit.</li> </ul> <p><b>Valid cGMP Certificate/quality control certificate/ quality assurance certificate/ Medical Device management certificate of the Principal Manufacturer for the quoted item/s as issued by relevant authority of the country of origin of the quoted imported good/s (duly attested from the Notary public (as the case may be) of the country of origin shall be verified via email from principal manufacturer and the principal manufacturer shall be bound to reply within 14 days. Non provision of this document shall lead to disqualification of the firm; and</b></p> <p><b>Valid Free Sale Certificate for the quoted item/s as issued by relevant authority of the country of origin of the quoted imported good/s issued by relevant authority of the country of origin of the quoted imported good/s (duly attested from the Notary public (as the case may be) of the country of origin shall be verified via email from principal manufacturer and the principal manufacturer shall be bound to reply within 14 days. Non provision of this document shall lead to disqualification of the firm; and</b></p>
9.	<p>The bidding Firm shall also provide an Affidavit on Judicial Stamp Paper of the value of at least Rs. 100/- (Rs. One Hundred Only) for the following undertaking:</p> <ul style="list-style-type: none"> <li>i. I / We have carefully read the whole set of Standard Bidding Documents for this bidding competition and that I / We have fully understood and agree to all the provisions (including, but not limited to, those provided under ITB 29.1 of the Bid Data Sheet), terms and conditions, evaluation criteria, mechanism of evaluation &amp; selection of items for which the Firm has applied for competition; and</li> <li>ii. I / We fully understand and agree that the bidding competition for which I / We have applied to enter in, shall be based on merit based scoring system for the evaluation of technical bids which has inverse relationship with the rates quoted by the bidders in their financial bids submitted; and that in this situation, the lowest financial bid/s may or may not win the bidding competition; and</li> <li>iii. I / We guarantee that the quoted drug / medicine items are, and shall be, freely available in the market of Pakistan; and particularly in the market of Khyber Pakhtunkhwa Province; and</li> <li>iv. I / We shall provide to the inspection team/s of expert/s authorized for the purpose by the Directorate General Health Services Khyber Pakhtunkhwa; an uninterrupted and free access to all relevant documents, sections of the manufacturing facilities / unit, storage and warehousing facilities as well as any other area relevant, as deemed appropriate by the above mentioned team for their purpose of visit/s.</li> <li>v. In case any documents submitted in relation to this bidding competition or any undertaking given by the Firm, if found incorrect or false or misleading or diverting the decision making for the competition, shall be liable to be proceeded for blacklisting for any business with / by the Government of Khyber Pakhtunkhwa, Health</li> </ul>

	<p>Department, confiscation of bids security and / or any other lawful action as deemed appropriate by the Government of Khyber Pakhtunkhwa, including that to be taken in concert with the DRAP or any other body / entity of the Federal Government; and</p> <p><b>vi.</b> I / We have fully understood that the medical devices and NDI shall be evaluated / examined by expert/s nominated by the Technical Evaluation Committee of the Health and Population Welfare Department, Khyber Pakhtunkhwa at its sole discretion; and that the Firm shall fully agree and abide by the decision / opinion, whatsoever, of the said expert/s regarding the selection, or otherwise, of the quoted item/s for purchase / rate contracting.</p> <p><b>vii.</b> I / We also undertake that submission of any false/bogus/fake/forged/ fabricated/tampered document shall lead to disqualification of our firm from this bidding competition as well as to other lawful action/s to be taken by the concerned authorities.</p> <p><b>viii.</b> I / We have fully understood that no such documents shall be entertained by the Procuring Agency, which is issued after due date of Bid opening.</p>
<b>10.</b>	<p>I certify and affirm that I have attached /provided all the requisite mandatory documents / information including Bids Security with this Bid and that I fully understand that any document if not provided / missing shall result in the disqualification and declaring my bid as ineligible and thus non-responsive.</p> <p>Signatures: _____</p> <p>Name: _____</p> <p>CNIC No. _____</p> <p>Designation: _____</p> <p>Address: _____</p>



## Form 1.1

### Financial Situation

*[The following table shall be filled in by the Bidder and for each partner of a Joint Venture / Consortium]*

Bidder's Legal Name: *[insert full name]*

Date: *[insert day, month, year]*

IFB No. and title: **(JPC/2019-20),,** Procurement of Contraceptives

Page *[insert page number]* of *[insert total number]* pages

#### 1. Financial data

Financial information in (PKR/US\$ equivalent in 000s)	previous <i>[insert number]</i> years, years information <i>[insert in words]</i> (PKR/US\$ equivalent in 000s)				
	Year 1	Year 2	Year 3	Year ...	Year n
Information from Balance Sheet					
Total Assets (TA)					
Total Liabilities (TL)					
Net Worth (NW) <sup>8</sup> (TA – TL)					
Current Assets (CA)					
Current Liabilities (CL)					
Working Capital <sup>9</sup> (CA – CL)					
Information from Income Statement					
Total Revenue (TR)					
Profits Before Taxes (PBT)					

#### 2. Financial documents

<sup>24</sup> **Net worth** is the difference between total assets and total liabilities. The **net worth** measures a firm's ability to produce profits over the long run as well as its ability to sustain losses.

<sup>95</sup> **Working capital** is the difference between current assets and current liabilities, and measures the firm's ability to generate cash in the short term.

The Bidder and its parties shall provide copies of the balance sheets and/or financial statements for *[number]* years pursuant Technical Evaluation Criteria, Sub-factor 2.1. The financial statements shall:

- (a) reflect the financial situation of the Applicant or partner to a JV/Consortium, and not sister or parent companies.
  - (b) be audited by a certified chartered accountant.
  - (c) be complete, including all notes to the financial statements.
  - (d) correspond to accounting periods already completed and audited (no statements for partial periods shall be requested or accepted).
- ☐ Attached are copies of financial statements, Income Tax Returns (balance sheets, including all related notes, and income statements) for the *[number]* years required above; and complying with the requirements

## Form 1.2

### Average Annual Turnover/Sales

*[The following table shall be filled in by the Bidder]*

Bidder's/Joint Venture Partner's Legal Name: *[insert full name]*

Date: *[insert day, month, year]*

IFB No. and title: *[insert IFB number and title]*

Page *[insert page number]* of *[insert total number]* pages

Annual turnover/sales data		
Year	Amount and Currency	PKR/US\$ equivalent
<i>[indicate year]</i>	<i>[insert amount and indicate currency]</i>	<i>[insert amount in PKR/US\$ equiv.]</i>
Average Annual Turnover *		

\* Average annual turnover calculated as total certified payments received for supplies in progress or completed, divided by the number of years specified at Technical Evaluation Criteria , Sub-Factor 2.2.

## Form 1.3

### Specific Experience

[The following table shall be filled in for contracts performed by the Bidder. Attach documentary proof with proper reference for the companies / organizations mentioned.]

Bidder's Legal Name: *[insert full name]*

Date: *[insert day, month, year]*

IFB No. and title: *[insert IFB number and title]*

Page *[insert page number]* of *[insert total number]* pages

<b>Similar Contract No.</b> <i>[insert number] of [insert number of similar contracts required]</i>	<b>Information</b>		
Contract Identification	<i>[insert contract name and number, if applicable]</i>		
Award date	<i>[insert day, month, year, i. e.,     /    -, 201 ]</i>		
Completion date	<i>[insert day, month, year, i.e., / - /, 201 ]</i>		
Role in Contract			
Total Contract Amount	<i>[insert total contract amount in local currency]</i>		PKR/US\$ <i>[insert total contract amount in PKR/US\$ equivalent]</i>
If partner in a JV/Consortium, or subcontractor, specify participation in total contract amount	<i>[insert a percentage amount]</i>	<i>[insert total contract amount in local currency]</i>	<i>[insert total contract amount in PKR/US\$ equivalent]</i>
Procuring Agency's Name:	<i>[insert full name]</i>		
Address:	<i>[indicate street / number / town or city / country]</i>		
Telephone/fax number	<i>[insert telephone/fax numbers, including country and city area codes]</i>		
E-mail:	<i>[insert e-mail address, if available]</i>		

## Form EXP – 1.3 (cont.)

### Specific Experience (cont.)

<b>Similar Contract No.</b> <i>[insert number] of [insert number of similar contracts required]</i>	<b>Information</b>
Description of the similarity in accordance with Sub-Factor 3.2 of Qualification Criteria.	
1. Amount	<i>[insert amount in PKR/US\$ in words and in Figures]</i>
2. Products	<i>[insert type and description of product]</i>

<b>Similar Contract No.</b> <i>[insert number] of [insert number of similar contracts required]</i>	<b>Information</b>
Description of the similarity in accordance with Sub-Factor 3.2 of Qualification Criteria:	
1. Amount	<i>[insert amount in PKR/US\$ in words and in Figures]</i>
2. Products	<i>[insert type and description of product]</i>

<b>Similar Contract No.</b> <i>[insert number] of [insert number of similar contracts required]</i>	<b>Information</b>
Description of the similarity in accordance with Sub-Factor 3.2 of Qualification Criteria:	
1. Amount	<i>[insert amount in PKR/US\$ in words and in Figures]</i>
2. Products	<i>[insert type and description of product]</i>

## Form EXP – 1.4

### Manufacturing Experience & Production Capacity

[The following table shall be filled in for contracts performed by the Bidder. Attach documentary proof with proper reference for the companies / organizations mentioned.]

Bidder's Legal Name: *[insert full name]*

Date: *[insert day, month, year]*

IFB No. and title: *[insert IFB number and title]*

Page *[insert page number]* of *[insert total number]* pages

1. Year Established:		
2. Key Personnel: [include name of candidate, position, professional qualifications, and experience]		
Technical	Production	Management
3. Products:		
Brand Name	Generic Name	Batch size
4. Dates, Numbers, and Expiration Dates of Current Licenses and Permits:		
5. Proof of product and facility registrations with purchaser's country regulatory authority and international agencies.		
6. Name of government agency(ies) responsible for inspecting and licensing of facilities in the country of origin of the raw material and or processing of the goods:		
Date of last inspection:		
7. Quality Assurance Certification (Please include a copy of your latest certificate with the Bid):		
8. Production capacity for the requested product: <i>[insert peak and average production capacity over the last three years in units/day or units/month, etc.]</i>		
9. List of names and addresses of sources of raw material used for the requested product.		

10. Proof of raw material product and facility registrations with manufacturer's country regulatory authority and international agencies.
11. Raw materials tested prior to use:
12. Presence and characteristics of in-house quality control laboratory
13. Names and addresses of external quality control laboratories used:
14. Are all finished products tested and released by quality control prior to release for sale? Yes                      No    If not, why?
15. Are control tests of the requested product done during production? If so list.
16. Procedures for dealing with rejected batches:
17. List tests conducted after production and prior to release of product on market:
18. List product recalls linked to defects of the requested product during the last 36 months. Include reason and date of recall.

## BID FORM 1.5 Firm's Past Performance<sup>10</sup>.

Name of the Firm:

Bid Reference No:

Date of opening of Bid: \_\_\_\_\_ **2019**

Assessment Period: (As Required in Evaluation Criteria)

Name of the Procuring Agency/Institution	Purchase Order No.	Description Of Order	Value of Order	Date of Completion	Procuring Agency's <sup>11</sup> Certificate
				As per agreement	
				As per agreement	

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<sup>10</sup> Bidders may use additional Sheets if required.

<sup>11</sup> All certificates are to be attached with this form.



## **Bid Form 2**

### **Letter of Intention**

*Bid Ref No.*

*Date of the Opening of Bids*

*Name of the Contract :{ Add name, e.g, Supply of Dugs and Medicines, etc.}*

To: *[Name and address of Procuring Agency]*

Dear Sir/Madam

Having examined the bidding documents, including Addenda Nos. *[insert numbers& Date of individual Addendum]*, the receipt of which is hereby acknowledged, we, the undersigned, offer to supply and deliver the Goods under the above-named Contract in full conformity with the said bidding documents and at the rates/unit prices described in the financial bid are not more than the trade price of quoted item/s in the market.

We undertake, if our bid is accepted, to deliver the Goods in accordance with terms and condition of contract agreement.

We agree to abide by this bid, for the Bid Validity Period specified in 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.

We undertake that, in competing for (and, if the award is made to us, in executing) the above contract, we will strictly observe the laws against fraud and corruption in force in Pakistan.

We, for any part of the contract resulting from this IFB, do not have any conflict of interest as mentioned in bid form 1.

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

Signed:

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

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

### **Bid Form-3**

#### **AFFIDAVIT (on Judicial Stamp Paper)**

I/We, the undersigned [**Name of the Supplier**] hereby solemnly declare and undertake that:

- 1) I / We, the undersigned, have read the contents of the Bidding Document and have fully understood it.
- 2) The Bid being submitted by the undersigned complies with the requirements enunciated in the bidding documents.
- 3) The Goods that I / We, the undersigned, propose to supply under this contract are eligible goods within the meaning of this SBD.
- 4) The undersigned are also eligible Bidders within the meaning of the Standard Bidding Documents.
- 5) The undersigned are solvent and competent to undertake the subject contract under the Laws of Pakistan.
- 6) The undersigned have not paid nor have agreed to pay, any Commissions or Gratuities to any official or agent related to this bid or award or contract.
- 7) The undersigned are not blacklisted or facing debarment from any Government, or its organization or project.
- 8) That undersigned has not employed any child labor in the organization/unit.
- 9) We understand that the Procuring Agency or any of its committees are not bound to accept the lowest or any other bid they may receive.

I / We affirm that the contents of this affidavit are correct to the best of my/our knowledge and belief.

Signatures with stamp

Name: \_\_\_\_\_

Designation: \_\_\_\_\_

CNIC No. \_\_\_\_\_

For Messrs. [**Name of Supplier**]

## **Bid Form-4**

**Note: This form is to be submitted in a separate sealed envelope to be kept within the main sealed envelope of the bid.**

### **Price Schedule format for Financial Bid of Joint Procurement of Contraceptives for the FY 2019-20**

1. **In case of Drugs/Medicines,** the unit price of each item shall be quoted and submitted in the following format:

S. No.	Serial No. of quoted item in IFB	Generic Name with Strength and Dosage Form of quoted Drug / Medicine	Trade Name of quoted Drug / Medicine	Trade Price of quoted (Unit price)	Rate Offered per unit in Pak. Rupees (Rs)
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2. **In case of Medical Devices and Non-Drug Items (NDIs),** the unit price of each item shall be quoted and submitted in the following format:

S. No.	Name of the Item	Unit Price (inclusive all applicable taxes)	No. of Units	Total Price	Discounts (if any)	Final Total Price (Inclusive of all taxes)
1	2	3	4	5	6	7
				3*4		5-6
	TOTAL					

## **Bid Form-5**

### **INTEGRITY PACT (on Judicial Stamp Paper)**

#### **Declaration of Fees, Commission and Brokerage Etc. Payable by Suppliers of Drugs/Medicines, Surgical Disposables, Medical Devices & Non Drugs Items for Joint Procurement of Contraceptives**

In response to advertisement related to the bidding process / competition regarding purchase and supply of drugs, non-drugs and surgical disposable items for **2019-20** for the health/population welfare facilities / institutions through Directorate General Health Services, Khyber Pakhtunkhwa, Peshawar, /Population Welfare Department, Khyber Pakhtunkhwa/ Merged Districts Khyber Pakhtunkhwa I, Mr. / Ms. \_\_\_\_\_ s/o, d/o \_\_\_\_\_ bearing CNIC No. \_\_\_\_\_, and having the Designation of \_\_\_\_\_ in

Messrs. (M/S) [**Name of Supplier**] do hereby solemnly affirm, declare and certify on behalf of M/S [**Name of Supplier**] that:

1. [**Name of Supplier**] has not obtained or induced the procurement of any contract, right, interest, privilege or other obligation or benefit from Government of Khyber Pakhtunkhwa (GoKP) or any administrative subdivision or agency thereof or any other entity owned or controlled by GoKP through any corrupt business practice; and
2. That without limiting the generality of the foregoing, [**Name of Supplier**] represents and warrants that it has fully declared the brokerage, commission, fees etc. paid or payable to anyone and not given or agreed to give and shall not give or agree to give to anyone within or outside Pakistan either directly or indirectly through any natural or juridical person, including its affiliate, agent, associate, broker, consultant, director, promoter, shareholder, sponsor or subsidiary, any commission, gratification, bribe, finder's fee or kickback, whether described as consultation fee or otherwise, with the object of obtaining or inducing the procurement of a contract, right, interest, privilege or other obligation or benefit in whatsoever form from GoKP, except that which has been expressly declared pursuant hereto; and
3. That [**Name of Supplier**] has made and will make full disclosure of all agreements and arrangements with all persons in respect of or related to the transaction with GoKP and has not taken any action or will not take any action to circumvent the above declaration, representation or warranty; and
4. That [**Name of Supplier**] accepts full responsibility and strict liability for making any false declaration, not making full disclosure, misrepresenting facts or taking any action likely to defeat the purpose of this declaration, representation and warranty. It agrees that any contract, right, interest, privilege or other obligation or benefit obtained or procured as aforesaid shall, without prejudice to any other rights and remedies available to GoKP under any law, contract or other instrument, be voidable at the option of GoKP; and
5. That not with standing any rights and remedies exercised by GoKP in this regard, [**Name of Supplier**] agrees to indemnify GoKP for any loss or damage incurred by it on account of its corrupt business practices and further pay compensation to GoKP in an amount equivalent to ten time the sum of any commission, gratification, bribe, finder's fee or kickback given by [name of Supplier] as aforesaid for the purpose of obtaining or inducing the procurement of any contract, right, interest, privilege or other obligation or benefit in whatsoever form from GoKP.

#### **Signatures with stamp**

**Name:** \_\_\_\_\_

**Designation:** \_\_\_\_\_

**CNIC No.** \_\_\_\_\_

**For Messrs. [**Name of Supplier**]**

**Witness No. 1**

**Witness No. 2**

(Signatures, name, father's name, CNIC & address of each Witness)

## **(Bid form-6)**

### **CONTRACT AGREEMENT (for successful bidders)**

**THIS RATE CONTRACT AGREEMENT** is made and agreed today on the \_\_\_ day of [Month], 2020 between the Project Director Integrated Health Project, Directorate General Health Services, Health Department, Government of Khyber Pakhtunkhwa or Director General Population Welfare Department, or Deputy Director Merged Districts, Government of Khyber Pakhtunkhwa (*hereinafter referred to as the Procuring Agency or first party, which expression shall, where the context admits, be deemed to include the successors and / or assignee/s of the Provincial Government of Khyber Pakhtunkhwa*); and Messrs. [Name of Supplier] through Mr. \_\_\_\_\_ Designation \_\_\_\_\_ CNIC No. \_\_\_\_\_, (*hereinafter referred to as the Supplier or second party or he or his or him, which expression, unless repugnant to the context, means and includes their legal heir/s, successors-in-interest, assignee/s and legal representative/s*) that:

**WHEREAS** the Procuring Agency has made a bidding competition under the approved Standard Bidding Documents for the year 2019-20 (*hereinafter referred to as the SBDs*) approved for Joint Procurement of Contraceptives, drugs/medicine, medical devices and other non-drug items (*hereinafter referred to as goods*) for actual purchases of the selected and rate contracted goods to be made by the offices / officers of the Health Department, or Population Welfare Department, Government of Khyber Pakhtunkhwa (*hereinafter called the Purchasing Agency or Purchasing Agencies or Purchasing Agency/ies, where the context so admits*); and

**WHEREAS** the Supplier has won the bidding competition for selected goods, as listed in the Schedule-1 of this contract agreement; and

**WHEREAS** the Supplier declares that he is, an authorized agent and Manufacturer and / or direct Importer of the goods for which he has won the bidding competition for supply of the same to the Purchasing Agency/ies, as defined in the SBDs, throughout the province of Khyber Pakhtunkhwa (*hereinafter referred to as the Province*); and

**WHEREAS** both the parties have agreed that the Purchasing Agencies in the Province shall purchase all, or some, or none of the goods, as of details given in the Schedule-1 of this Contract Agreement, from the Supplier at the sole discretion of the individual Purchasing Agency/ies in subordination to and laws and matters ancillary to the terms and conditions of the SBDs; and

**WHEREAS** the Supplier shall supply all the goods ordered by the Purchasing Agency/ies to the later in the quantity as mentioned in the supply order to be issued by the Purchasing Agency within the timeframe as mentioned in clause-22 of this contract agreement;

**Now, therefore,** both the parties hereby mutually agree to enter into this contract agreement as under:

1. The Supplier agrees to take full responsibility of the validity and implications, that may arise in future, of declaration as submitted by him through an affidavit on judicial stamp paper along with the Bid Form-1 of the SBDs along with his bid; and also that in case of any kind of breach of the said declaration, the Supplier shall be liable to be proceeded against by the concerned Procuring Agency, as the case may be, in accordance with the clauses of this rate contract agreement as well as relevant laws, rules and regulations of the Government of Khyber Pakhtunkhwa, as amended from time to time, to govern the situation/s.
2. The Supplier shall supply the ordered goods to the concerned Procuring Agency exactly at the address of the official premises as provided in the supply order issued to the former.
3. The Supplier shall be solely responsible for the safe and appropriate method and mode of transportation, loading and / or unloading and stacking of the supplied items till, and at the time of delivery to the destination address indicated by the concerned Procuring Agency.

4. The Supplier shall be solely responsible for any damage or untoward incident, maintenance of required temperature and protection from light and other environmental conditions as well as other hazards that may possibly or potentially affect the safety, quality and efficacy of the supplied goods till the time of delivery and the consequences arising therefrom, if any.
5. The Supplier shall not claim or charge any transportation, loading / unloading, labour or any other charges, whatsoever, related to or in the name of logistics, accidents, insurance, freight, toll tax, etc.
6. The Supplier shall supply all the goods in full conformity to the specifications as laid down in the SBDs.
7. The concerned Procuring Agency shall arrange to obtain randomized sample/s for each item of the supplied goods, if deemed appropriate, as in the SBDs and belonging to the categories of drug/medicine, medical devices through the notified Inspection Committee at the cost of Supplier from the concerned Drug Testing Laboratory for Test / Analysis as provided in the Drugs Act 1976, DRAP Act 2012 and rules frame thereunder as well as provisions of the SBDs. However in case of IUCD, Condoms and Implants the tests/analysis report will be required for each batch from UNFPA / WHO accredited lab at the cost of supplier, further subject to the condition/s that:
  - a. The supplied goods declared in contravention to any provision of the Drugs Act 1976, DRAP Act 2012 and rules framed thereunder, shall be replaced by the Supplier at his sole risk and cost and at no cost to the concerned Procuring Agency, within 07 days from the date of intimation to the Supplier and / or his focal person, as nominated by the Supplier in the Bid Form-1 of his bid submitted under the SBDs, at such place/s as the Purchasing Agency may direct in accordance with clause-2 of this contract agreement.
  - b. In case of IUCD, Condoms and Implants if the concerned Procuring Agency consider appropriate to re-send random batch/s of IUCD, Condoms and Implants to UNFPA / WHO accredited lab at the cost of supplier for verification confirming the quality of the commodities.
  - c. The concerned Procuring Agency shall arrange to obtain sample/s of the replaced goods as in clause-7 (a) above, for the purpose of Test / Analysis as provided in the Drugs Act 1976, DRAP Act 2012 and rules frame thereunder.
  - d. In case of non-supply or delayed supply or partial supply of replacement items, as in clause-7 (a) above, the Supplier shall be liable for imposition of penalty/ies as provided in clause-22 of this contract agreement.
  - e. All the contravened stock of goods, as in clause-7(a) above, if seized by the authorities or Drug Inspector concerned, shall be the case property under the provisions contained in the Drugs Act, 1976 and the rules framed thereunder.
  - f. The supplier shall be responsible to make arrangements for appropriate storage and the matters ancillary to the safe custody of the seized case property as in clause-7(d) above at his sole risk, cost and responsibility with no claim, whatsoever, from the concerned Purchasing Agency, and / or the Drug Inspector, and / or Procuring Agency.
  - g. In case the destruction of the seized stock, as in clause-7(d),(e) above, is required to be undertaken under the applicable laws and rules, all the costs involved in the execution of the decision and destruction, whatsoever, shall be solely borne by the supplier without any claim of any nature, whatsoever, from the concerned Procuring Agency or Drug Inspector or Procuring Agency.
  - h. Any of the item/s, as in clause-7 above, if initially declared to be in contravention with the provision/s of Drugs Act 1976, but later on declared as of standard quality by the concerned Appellate Drugs Testing Laboratory, shall be returned to the supplier by the concerned Drug Inspector in a lawful manner.

8. Supplier shall supply to the concerned Procuring Agency/ies, the freshly manufactured goods having maximum possible long expiry dates with the minimum remaining shelf life of at least 75% in case of imported goods and at least 85% in case of locally manufactured goods within Pakistan.
9. In case of taking any action contravening to any provision/s of the applicable law/s and rules, the Supplier shall render himself liable to such lawful action/s as deemed appropriate and taken against him under any or all the applicable law/s, rule/s of the Government of Khyber Pakhtunkhwa, terms and conditions of the SBDs and the clauses of this contract agreement.
10. The concerned Procuring Agency/ies shall take legal / lawful action against the Supplier regarding non-supply, short supply, substituted supply, delayed supply or any other unlawful action / shortcoming, on the part of Supplier, pertaining to the Drugs Act 1976 and / or the execution of this contract agreement.
11. The concerned Procuring Agency shall take lawful / legal action against the Supplier in accordance with the clauses of this contract agreement as well as relevant and applicable laws, rules and regulations of the Government of Khyber Pakhtunkhwa, as amended from time to time, to govern suchlike situation/s, which may, inter alia, include but not limited to blacklisting, forfeiture of earnest money and performance guarantee, if any.
12. The Supplier agrees to the following conditions related to packing, packaging and labelling of the goods to be supplied to Purchasing Agencies under this contract agreement:

- a. The bidder shall supply the Contraceptives in special green packing with Logo of the Government of Khyber Pakhtunkhwa. The following wording/insignia shall be printed in bold letters both in Urdu & English in indelible red color ink on each carton, pack, blister, vial / ampoule and immediate container etc.

**For Department of Health:**

“NOT FOR SALE”

“DOH: Govt. of Khyber Pakhtunkhwa”

**For Population Welfare Department:**

“NOT FOR SALE”

“PWD: Govt. of Khyber Pakhtunkhwa”

- b. The labels shall comply with all the requirements as laid down under the Drugs Labelling and Packing Rules 1986. The strip / blister shall clearly indicate expiry date of the same medicine in a clear and legible manner.
  - c. The goods shall be packed and transported to the concerned Procuring Agency in accordance with the provisions contained in the Standard Bidding Documents.
13. The concerned Procuring Agency or its representative shall have the right to inspect the manufacturing facility, premises, warehouse/s, godown/s, laboratories etc. at any time during the financial year 2019-20 and/or till the execution of supply orders given under this contract agreement by the concerned Procuring Agency/ies of the Province. If anything found in contravention of cGMP, clauses of Drug Act 1976 and/or this Contract Agreement the concerned Procuring Agency shall have the sole right and authority to take any lawful action as deemed appropriate, against the Supplier which may include, but not limited to cancellation of supply

order/ orders given to the Supplier by the Purchasing Agency/ies as well as imposition of penalties, forfeiture of supplied stock, forfeiture of performance guarantee and /or earnest money as the case may be, stoppage and/or recovery of payment made to the supplier as well as taking any other lawful action.

14. The Supplier agrees that the approved price of all individual items in Schedule-1 of this contract agreement, as quoted by him in the financial bid, shall remain valid till and up to 30<sup>th</sup> June 2020.
15. The Supplier shall provide legal and valid warranty to the Purchasing Agency for all the goods supplied under this contract agreement, which fall under the provisions of Drugs Act 1976, DRAP Act 2012 and the rules framed thereunder, on prescribed Form-2A in accordance with the mechanism prescribed for the purpose.
16. For Non-Drug Items, the Supplier shall provide appropriate warranty to the Purchasing Agency/ies in accordance with Special Conditions of Contract of the SBDs for this bidding competition, for each item supplied in response to supply orders.
17. In case the Supplier had been awarded marks during the technical evaluation for Active Pharmaceutical Ingredients (API) source accreditation for Drugs / Medicines, and for medical grade material certification for medical devices & Non-Drug Items, and for Pharmaceutical grade certification for immediate containers of Drugs/medicines shall warranty the supply of all such goods with the same certified quality, material and specification/s to the Purchasing Agency/ies throughout the validity period of this contract agreement.
18. Bill for payment in triplicate along with all other relevant and required documents shall be submitted by the Supplier to the concerned Procuring Agency/ies immediately after completion of supply of ordered stock. The Supplier shall be bound to pay all sorts of government taxes, duties and stamp duties, imposed earlier or during the financial year by the Government of Pakistan and / or by the Provincial Government of Khyber Pakhtunkhwa or any other tax levied at the concerned port on any supplied / purchased item.
19. In case of situation related to Force Majeure, the Supplier may immediately without delay inform the concerned Procuring Agency in writing about the situation along with solid proof of the situation through the fastest, lawful and available means of communication, but not through the electronic mail, and request the Procuring Agency for the grant of extension in the supply period.
  - a. The Procuring Agency, in case of being fully satisfied with the genuineness of situation arising from the claimed Force Majeure by the Supplier, may extend the period of supply of goods up to a maximum of not more than thirty days.
  - b. The Procuring Agency shall, in no case, be responsible or held responsible for any complications in making payments to Supplier that may arise from the closure of financial year, and / or lapse, and / or surrender of public funds, vis-à-vis, the standard and normal public sector financial management laws, rules, regulations, procedures and practices governing the Procuring Agency.
  - c. After the expiry of extended period as in clause-19(a), the supply order shall stand cancelled to the extent of non-supplied goods and the performance security, as specified in the SBDs shall be forfeited in favour of the concerned Procuring Agency.
20. The Supplier agrees that the supply of the ordered goods under this agreement shall be completed by the Supplier within Ninety (90) days for local manufacturers and one hundred and twenty(120) days for imported items after the receipt of supply order/s from the Purchasing Agency/ies, except in situation/s covered under clause-19 above regarding Force Majeure. In case of delay in supplies reaching to the Purchasing Agency, the following penalties shall be imposed by the Purchasing Agency upon the Supplier:



In case the Supplier fails to make deliveries as per purchase order and within the time frame as stipulated in the Schedule of Requirement, proceedings shall be initiated against the defaulter which may result into forfeiture of the performance guarantee and blacklisting of the supplier.

In case of delay in delivery of goods beyond the periods specified in the Schedule of Requirements and subsequent purchase order, a penalty @ 0.067% per day of the cost of late delivered supply shall be imposed upon the Supplier to the extent of 15 days (after delivery period) and @ 0.080% per day for further 15 days (Total 30 days). In case of further inordinate delay, the issue will be placed before the purchase committee for decision.

In order for the penalty to take effect, the counting of days to start from the opening of letter of credit or approval of art work (whichever is later). Purchase order/s will be shaped accordingly as per the foregoing.

a. In case of delay in supply beyond the timeline specified in 20 (a) (b), the supply order issued by the concerned Procuring Agency shall stand cancelled to the extent of non-supplied items and in such a case, the Procuring Agency shall have the right, duty and authority to impose any or all of the below mentioned penalties; that is

- i. Forfeiting the bids security and / or performance guarantee of the Supplier as related to this contract agreement; and / or
- ii. Immediately debarring the Supplier from future participation and business for at least next three (03) calendar years with the Government of Khyber Pakhtunkhwa through concerned Procuring Agency, as defined in the SBDs.
- iii. Initiating the process for and recommending for permanent blacklisting of the Supplier with the concerned Procuring Agencies.

21. Notwithstanding any rights, duties and / or remedial measures and / or managerial actions taken and / or to be taken and / or any powers exercised and / or to be exercised by the Procuring Agency and / or Purchasing Officer/s with regard to the execution of this contract agreement, the Supplier agrees to indemnify all of them for any loss or damage incurred or inflicted upon by them in individual or official capacity upon the Supplier whether through any of their actions and / or practices and / or otherwise.
22. The Supplier further agrees to pay compensation to the Government of Khyber Pakhtunkhwa of an amount equivalent to ten times the sum of any commission, gratification, bribe or kickback and / or finder's fee given by the Supplier for the purpose of obtaining and / or inducing the procurement of any contract, right, interest, privilege or other obligation/s or benefit/s in whatsoever form, from the Procuring Agency or any of the Purchasing Agencies.
23. The Procuring Agency and / or Purchasing Agency, as the case may be, and the Supplier shall make every effort to resolve amicably by direct negotiation any disagreement or dispute arising between them under or in connection with the contract / supplies. However, despite such negotiation if the Purchasing Agency & Supplier have been unable to resolve amicably a contract dispute, either party may refer the case to Secretary to Government of Khyber Pakhtunkhwa, Health Department, Peshawar for decision through a Dispute Resolution Committee under the chairmanship of Special Secretary Health with Additional Secretary Health (Development) or Additional Secretary Health (Establishment) and Deputy Secretary Drugs as members.

<p>Project Director Integrated Health Project, Directorate General Health Services Khyber Pakhtunkhwa Or/and Director General Population Welfare Department, Khyber Pakhtunkhwa For and on behalf of Government of Khyber Pakhtunkhwa, Peshawar or/and Deputy Director Merged Districts Population Welfare Department, Khyber Pakhtunkhwa For and on behalf of Government of Khyber Pakhtunkhwa</p>	<p>Signature: _____ Name: Designation CNIC No. Stamp: For and on behalf of Manufacturers / Importer</p>
<p>WITNESS NO. 1 Signature: Name: Designation: Address: CNIC No.</p>	<p>WITNESS NO. 2 Signature: Name: Father's Name: Address: CNIC No.</p>

## List of WHO Pre-qualified Labs for contraceptive quality control

No	Quality Control Test Facility	Product
1	<p>FHI 360 Product Quality and Compliance 2810 Meridian Parkway, Suite 160 Durham, NC 27713 USA Emails: shamel@fhi360.org, jtremelling@fhi360.org</p> <p><u>Bangkok Laboratory:</u> FHI 360 Product Quality and Compliance Bangkok, Thailand Emails: shamel@fhi360.org, jtremelling@fhi360.org</p>	Male and female condoms Oral and injectable contraceptives IUDs
2	<p>Enersol 235 Nelson Street, Annandale, NSW 2038 AUSTRALIA Phone: (+61) 2 9552 1707 Fax: (+61) 2 9552 1709 E-mail: enquiries@enersol.com.au</p> <p><u>Malaysian Laboratory:</u> Enersol No. 2-2, Lebuuh Sungai Pinang 1, Seksyen 8, Bandar Georgetown, Daerah Timur Laut, 11600 Pulau Pinang, MALAYSIA Phone: (+60) 4 281 1371 Fax: (+60) 4 281 1372 E-mail: enquiries@enersol.com.au</p>	Male and female condoms IUDs, Syringes, Infusion sets, needles, blood bags, catheters and gloves
3	<p>Valendor AB Vargmötesvägen 4 186 30 Vallentuna Sweden Phone: +46(0)8 514 302 44 www.valendor.se</p>	Male and female condoms Gloves
4	<p>SGS Lab Simon S. A. Vieux Chemin du Poète 10 B-1301 Wavre Belgium Tel: +32 10 421111; +32 10 42176; Fax: +32 10 421100 e-mail: be.lifeqc@sgs.com wim.vanimmerseel@sgs.com</p>	Male and female condoms
5	<p>TÜV SÜD PSB Pte Ltd Chemical &amp; Materials (Food &amp; Pharmaceutical Testing) 1 Science Park Drive Singapore 118221 Tel: +65 68851313 Fax: +65 67784301 e-mail: enquiries@tuv-sud-psb.sg , <a href="http://www.tuv-sud-psb.sg">http://www.tuv-sud-psb.sg</a></p>	Male and female condoms, IUDs, Pharmaceutical Hormonal Contraceptives