Contraceptive Procurement Manual

Health and Population Welfare Departments,
Government of Khyber Pakhtunkhwa

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Abstract

The Khyber Pakhtunkhwa Public Procurement Regulatory Authority team has examined the manual carefully and made every effort to synchronize this manual with Khyber Pakhtunkhwa *Public Procurement Rules (PPR), 2014*, regulations, standard bidding documents (SBDs), and policy instructions issued from time-to-time. However, if any provisions or the interpretation of KPP rules, regulations etc., cited in this manual conflict with the *KPP Rules, 2014*, regulations, SBDs and/or policy instruction issued by the Authority from time-to-time, shall prevail.

Contents

Acronyms

ADB	Asian Development Bank
AQL	acceptable quality level
AWB	air waybill
B/L	bill of lading
BDS	Bid Data Sheet
BEC	Bid Evaluation Committee
BER	Bid Evaluation Report
BOS	Bid Opening Sheet
CFR	cost and freight
CIF	cost, insurance and freight
CPT	Carriage Paid To
CIP	Carriage And Insurance Paid To
DC	direct contracting
DAP	Delivered At Place
DAT	Delivered At Terminal
DDP	Delivered Duty Paid
DoH	Department of Health
DRAP	Drugs Regulatory Authority of Pakistan
EPI	Expanded Programme of Immunization
ETA	estimated time of arrival
EU	European Union
EXW	Ex Works
FOB	Free On Board
FAS	Free Alongside Ship
FY	fiscal year
GCC	General Conditions of Contract
GOP	Government of Pakistan
GMP	good manufacturing practice
HTS	Harmonized Tariff System

ICB	International Competitive Bidding
ICC	International Chamber of Commerce
IFB	Invitation for Bid
Incoterms	International Commercial Terms
INN	international nonproprietary name
ISO	International Standards Organization
ITB	instructions to bidder
IUD	intrauterine device
KPPR	Khyber Pakhtunkhwa Public Procurement Rules
L/C	letter of credit
L/D	liquidated damages
LCA	letter of credit authorization
LDPE	low density polyethylene
LIB	Limited International Bidding
MOH	Ministry of Health
NCB	National Competitive Bidding
NOA	Notification of Award
NCA	National Control Authority
OCB	Open Competitive Bidding
PPRA	Public Procurement Regulatory Authority
QA	quality assurance
QC	quality control
RFP	request for proposal
RFQ	request for quote
SBD	standard bidding document
SBEF	Standard Bid Evaluation Form
SCC	Special Conditions of Contract
UNFPA	United Nations Population Fund
UNICEF	United Nations Children's Fund
U.S.	United States
VAT	value-added tax
WHO	World Health Organization

Acknowledgement

The *Contraceptives Procurement Manual* of Khyber Pakhtunkhwa was developed with the support of all relevant public sector stakeholders, including the Khyber Pakhtunkhwa Public Procurement Regulatory Authority, development partners, health specialists, and medical professionals. We gratefully acknowledge their dedicated efforts in reviewing, contributing to, and supporting the development of this manual.

We sincerely appreciate the valuable support extended by USAID | Pakistan to strengthen the health sector of the Khyber Pakhtunkhwa province. We wish to thank Mr. Randolph Augustin, Director, Health Office. USAID | Pakistan, for his leadership and coordinated support for the USAID | DELIVER PROJECT as they successfully developed this manual.

We also wish to express our appreciation for the tireless efforts made by Dr. Muhammad Tariq, Country Director, USAID | DELIVER PROJECT in Pakistan, and his dedicated team, in developing the *Contraceptives Procurement Manual.*

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Foreword

The *Contraceptives Procurement Manual* will be a beacon of light and a valuable resource for the officers and staff of the Population Welfare Department and the Department of Health of the Government of Khyber Pakhtunkhwa, who are responsible for procuring contraceptives from the global market. The procurement and use of quality contraceptives is essential if Pakistan is to achieve the goals of our family planning and reproductive health programs.

This manual derives its strength from the rules framed by the Khyber Pakhtunkhwa Public Procurement Regulatory Authority, and internationally recognized principles of procurement; which encourage transparency, accountability, and efficiency in the procurement process. It addresses the key phases of the procurement cycle, beginning with procurement planning and publishing of invitations for bids to bid evaluation, in accordance with the established criteria; selection of the supplier; and, finally, the award of contract and monitoring of supplier compliance. The manual guides the procurement staff at each stage of the process as they learn to respond to different situations. It guides the heads of procuring units on how to support and carry forward the procurement process for contraceptives.

The manual also includes supplementary material—for example, information on pre-qualification and pre-shipment—which can significantly help in the effective implementation of public sector procurement of contraceptives.

Key provincial stakeholders have reviewed the *Contraceptives Procurement Manual*, including representatives from the Population Welfare Department and Department of Health, Government of Khyber Pakhtunkhwa, to ensure that it meets their requirements and needs. The manual completely complies with the Khyber Pakhtunkhwa Public Procurement Rules of 2014; KPPRA has endorsed it.

We would like to extend our appreciation to USAID | Pakistan for providing financial support to the USAID | DELIVER PROJECT, which enabled them to develop the manual. The use and application of the procurement procedures described in this manual by responsible procuring agencies will ensure that the people of Khyber Pakhtunkhwa have easy access to quality contraceptive products, enabling them to have healthy timing and spacing of pregnancy.

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Introduction

The Contraceptive Procurement Manual has been developed to provide the Government of Khyber Pakhtunkhwa Population Welfare and Health Department's procurement personnel with the information and instructions needed to procure contraceptives of good quality on the international market to support the coordinated goals of the Government of Khyber Pakhtunkhwa towards improving maternal and child health in the province. The Contraceptive Procurement Manual incorporates best international procurement practices that help promote transparency, accountability and efficiency in the public sector procurement process. The Procurement Manual addresses the key phases of the procurement cycle, from procurement planning and issuing invitations to bid, to bid evaluation, supplier selection, contract award and management.

The primary audience for the Contraceptive Procurement Manual is procurement officers and other direct procurement staff who are assigned responsibility for procuring quality contraceptives. The Procurement Manual provides these personnel with step-by-step instructions for completing standard bidding documents, opening bids from suppliers, evaluating supplier bids and monitoring supplier performance. The manual also includes supplementary materials, such as information on pre-qualification and pre-shipment compliance programs, which are designed to support procurement officers in effectively implementing public sector procurement of contraceptives.

The Contraceptive Procurement Manual also provides pertinent information for policymakers and mid-level decision makers who are not required to understand the detailed procedures of the procurement process, but should understand the overall procurement process for contraceptives and the role they can play to help ensure the procurement process is effectively implemented. It is recommended that this audience review Appendix V: Summary Guide for Policymakers, Directors and Managers.

The Contraceptive Procurement Manual also includes key reference documents, such as the Khyber Pakhtunkhwa Public Procurement of Goods, Works and Services Rules 2014, Khyber Pakhtunkhwa Public Procurement Regulatory Authority Act 2012 and the Drugs (Labeling and Packing) Rules 1986, to ensure that procurement officers have access to original resource documents as they prepare for and conduct public sector procurement of contraceptives.

Users of the Contraceptive Procurement Manual are encouraged to thoroughly review the Manual in order to fully understand the breadth and scope of the information it contains so that they can be fully prepared to conduct effective public sector procurement of quality contraceptives for the people of Khyber Pakhtunkhwa.

Procurement Basics

Procurement Basics include:

A. Introduction
B. Principles of Good Public Sector Procurement
C. Principles of Competitive Bidding
D. Procurement Policy Guidelines
E. Procurement Methods - Goods (Contraceptives)
F. Rules and Tools for Procurement of Goods (Contraceptives)
G. Procurement Plans
H. Quality Assurance
I. INCOTERMS - for International Procurement
J. Letters of Credit and Other Payment Options
K. Specifications
L. Timeline for Procurement
M. Code of Ethics

A. Introduction

The procurement basics section of this manual includes fundamental information on the principles, policies, and rules that guide good public sector procurement practices. This section also includes information on other important topics—quality assurance (QA) and specifications that support effective public sector procurement. These procurement basics are applicable to procurement for any healthcare commodity.

B. Principles of Good Public Sector Procurement

The Government of Khyber Pakhtunkhwa (GoKPK) Public Procurement Regulatory Authority (PPRA) Act 2012 and Public Procurement of Goods, Works and Services Rules (PPR) 2014 are based on well-established and widely accepted principles of good public sector procurement:

Economy, Efficiency, Equality, Fairness, Transparency

Properly administered, open competition (competitive bidding) fulfills these requirements and is the backbone of good public sector procurement.

C. Principles of Competitive Bidding

1. Suitable Package

Design bid requirements to attract the interest of both large and small foreign and domestic suppliers. While partial bids are acceptable, always define parts that must be bid together and those that can be bid alone.

2. Early Warning

National Competitive Bidding (NCB) allows bidders at least 15 days to submit offers. International Competitive Bidding (ICB) allows bidders at least 30 days to submit offers (*Rule 34 of PPR 2014*).

3. Non-discrimination

Invite bids from as many foreign and domestic suppliers as possible using open advertising in newspapers, trade journals and websites in accordance with procurement methods as defined by the *Rule 11 of PPR 2014*.

4. Accessibility

Allow wide access to competition by setting reasonable costs for bidding documents and securities; respond in writing to all written questions and requests for additional information from each bidder as soon as possible; provide identical information to all other bidders, but do not identify the source of the inquiry.

5. Neutrality

Use generic terms to describe the specifications. Do not show preference for a specific brand or manufacturer in specifications; include the phrase *or equivalent* if a brand name, trademark or catalogue number must be used.

6. Formality

Require that bids be in writing, signed and received in sealed envelopes before a stated date and hour.

7. Confidentiality

Do not open the bids before the assigned date and time (*Rule 37 of PPR, 2014*). Restrict all bid information to authorized parties.

8. Consistency

Evaluate all bids against the same criteria and the terms and conditions set forth in the bidding documents. Do not ask or permit a bidder to change the substance of the bid after the submission deadline. Bidders may only ask for clarification that will not change the substance of the bid (*Rule 37 of PPR, 2014*).

9. Objectivity

Determine if each bid is *substantially responsive* by checking for errors, correct signatures, inclusion of all required documents and adherence to basic bidding requirements. Select the most advantageous bid based on both the price and the evaluation criteria announced in the bidding documents.

10. No Negotiation before Award

Obtain the lowest responsible offer from each bidder through the competitive bidding process. In most cases there should be no negotiation before award, however, a procuring entity may engage in negotiated tendering with one or more suppliers without prior publication of a procurement advertisement when supplies involved are manufactured purely for supporting specific research, for technical or artistic reasons, or for reasons of extreme urgency. (See *Rule 10 (d) of PPR 2014* for additional information)

D. Procurement Policy Guidelines

The Government of Khyber Pakhtunkhwa has established clear procurement rules (*PPR-2014*) that offer general guidance to personnel procuring goods and services for public sector organizations, including health and population sectors. These guidelines include general principles, such as evaluation of bids based on the best value for the money, as opposed to the lowest price; and a preference for Pakistani suppliers, as per government policy. The complete set of procurement rules are in appendix 1, which contain the PPR-2014 and appendix 2, which contain the KPPRA Act 2012.

E. Procurement Methods - Goods

The Government of Khyber Pakhtunkhwa, when purchasing entities, requires that the most appropriate method of procurement be used for a specific purpose. The Government of Khyber Pakhtunkhwa procurement methods align with traditional public sector procurement practices—as the estimated value of the future contract increases, more stringent and documented procurement methods are required. For example, for procurements with an estimated value of less than 50,000 rupees simplified petty purchase procedures can be followed; but, for procurements with an estimated cost equivalent to Rs 100,000 or above, the more complex and documented international competitive bidding procedures is the default method of procurement Rule 14 (2)(a) of PPR 2014. However, non-monetary issues—such as a limited number of suppliers worldwide or within the country—can also have a role in selecting procurement methods. The main methods for procuring medicines and supplies are as follows.

1. International Competitive Bidding (ICB)

This open, or unrestricted, bidding process includes international sources. Bids are solicited by advertising an open invitation to suppliers around the world. Bids are invited internationally through the PPRA website, the procuring agency's website, and other internationally recognized procurement advertisement websites. All suppliers are invited to participate in the bidding process—*Rule 41 of PPR, 2014*.

In modules 2–5 of this manual ICB is explained, in detail.

2. Pre-qualification of Bidders

Rule 8 of PPR-2014 allow for the prequalification of suppliers in case of services, civil works, and turnkey projects; also, when the procurement is for expensive and technically complex equipment and medicines; and complex services, with a precondition that only technically and financially capable firms that show adequate managerial capability are invited to submit bids. Prequalification is widely advertised—this formal process offers the opportunity to pre-qualify. Before the procurement process, the applicants submit information on their technical, financial, performance history, and manufacturing capacity for the purchaser to evaluate. Only prequalified firms are invited to bid, instead of open advertisement; but, the rest of the procurement process is exactly the same as for ICB.

Procedure for prequalification of potential bidders is described in *Rule 8 of PPR-2014* (see appendix 1).

See appendix 7 for information about the pre-qualification of contraceptives.

3. Open Competitive Bidding (OCB)

This is open, unrestricted, and is usually for national sources only. It is based on the *PPR 2014*; procedures are described in *Rule 6 of PPR 2014*.

4. Request for Quotation (RFQ)

Rule 10 of PPR-2014 allows RFQs to be issued for procurement action that is less than 100,000 rupees and above the financial limit prescribed for petty purchases. With this method, quotations are requested and received from a limited number of suppliers, but not less than three; price and contents are compared; and the contract is awarded, based on the lowest evaluated cost.

5. Petty Purchases

This method is allowed by *Rule 10 of PPR 2014* for goods with a value of less than 50,000 rupees. Petty purchases are exempt from the requirements of bidding or the quotation of prices.

6. Direct Contracting (DC)

With DC, price and terms are agreed to with one chosen supplier, without asking others for bids (e.g., without competition). *Rule 10 of PPR 2014* limits the use of DC. It is allowed only in certain circumstances; for example, when there is only one producer/supplier in the country for NCB; or, in the world, for ICB. Pre-approval is required.

7. Negotiated Tendering

Rule 10 of PPR 2014 also allows for negotiated tendering with one or more suppliers without prior publication of a procurement advertisement under certain conditions, such as extreme urgency. See *Rule 10 of PPR 2014* for additional information on allowed circumstances for negotiated tendering.

F. Rules and Tools for Procurement of Goods/Contraceptives

1. Rules for Procurement of Goods

a. Khyber Pakhtunkhwa Public Procurement Rules 2014

The Procurement Regulatory Authority, Government of Khyber Pakhtunkhwa, has developed and adopted a set of procurement rules— Khyber Pakhtunkhwa Public Procurement Rules, 2014— which are based on widely acknowledged principles of good public procurement practice. These rules are applicable to all procurement involving public funds, subject to an exception—if the regulations conflict with an international obligation or agreement, the provisions of that agreement prevail.

PPR 2014 covers the organization of public procurement, basic procurement rules, and a choice of procurement methods. Procurement detail is based on National OCB. In addition, Section 35 of the Khyber Pakhtunkhwa Public Procurement Regulatory Authority Act, 2012 describe the process for complaints and appeals.

b. The Khyber Pakhtunkhwa Public Procurement Regulatory Authority Act 2012

The *PPRA Act 2012* has laid down the general principles of public procurement under clause 3: "*All public procurement shall be conducted in such a manner as provided in this Act, rules and regulations made*

under this Act and shall promote the principles of transparency, economy, value for money, accountability and swift grievance handling."

c. The Drugs (Labeling and Packing) Rules, 1986

The Drug (labeling and packing) Rules, 1986 describe requirements for labeling and packing of drugs that will be registered in Pakistan under the Drug Act 1976. See appendix 2 for a copy of the Drug Rules, 1986.

2. Tools for Procurement of Contraceptives

The main tools applicable for the procurement of goods/contraceptives are the *standard bidding documents* (SBD) used by the Government of Khyber Pakhtunkhwa departments and those offered by the World Bank.

a. Government of Khyber Pakhtunkhwa Standard Bidding Documents

The Department of Health (DoH) Khyber Pakhtunkhwa developed standard bidding documents for use in national OCB.

All relevant tools for procuring contraceptives are part of this manual. This manual also includes relevant and useful forms and information from *Procurement Policies and Standard Operating Procedures: NHF Programs*, used by the former Ministries of Health and Population Welfare.

G. Procurement Plan (PP)

When procuring, *Rule 30 of PPR 2014* requires that an annual (or annually updated, project-wide) procurement plan be submitted for approval before any procurement can take place. The plan includes a broad description of the commodities to be purchased, a budget and source of the budget, a time frame when the goods will be procured, and the method of procurement. Procurement planning is also explained in module 1.

H. Quality Assurance

This manual focuses on procurement of quality contraceptive commodities. The quality of the products is an important component of an overall approach to quality of care within a family planning program. The consequences of poor quality products include lack of therapeutic effect, as well as possible adverse health consequences; even the perception of poor quality can severely compromise the credibility of an otherwise successful family planning program. For these reasons, ensuring the quality of contraceptive products is critical.

The QA process is more than a simple visual inspection of a product for defects. It spans a range of activities that includes product development to the end user.

In discussing product quality there are three terms—QA, good manufacturing practices (GMP), and quality control (QC)—that are often used interchangeably. While these activities complement and support one another, the terms are still distinctly different.

Quality assurance is usually understood to be the sum of all activities and responsibilities that will ensure that products meet all their applicable quality specifications.

GMPs are the part of QA that ensures products are consistently produced and controlled to the quality standards appropriate for their intended use and as required by the governing National Regulatory

Authority (NRA). GMPs are primarily intended to reduce the risks inherent in production that cannot be completely prevented by testing the final products.

Quality control is the part of GMPs that focuses on product sampling, specification review, and product testing. Quality control also includes the documentation and release procedures that ensure all necessary tests are completed before materials are released for use or products are released for sale; and until their quality has been determined to be satisfactory.

Several parties share the responsibility for ensuring product quality: product developer, manufacturer, NRA, procurement agency, logistics system, and end user. The role of the procurement agency is briefly described below.

In accordance with national legislation, procurement should be limited to only those products approved by the national drug regulatory authority. The procurement unit has a significant impact on product quality by establishing well-defined contract specifications for the products it procures. Specifications should require certification that the manufacturer has complied with GMP, that the product is registered in the country where it will be used, and that it meets local regulatory requirements. In addition, contract specifications should describe the desired physical characteristics of the product, as well as specify the pre-shipment inspection and any test requirements against which the product will be evaluated before the manufacturer ships it. See appendix 5: Product Quality Assurance, for additional information on QA.

I. International Commercial Terms (Incoterms) for International Procurement

International Commercial Terms (Incoterms) are primarily used for international procurements. Terms—such as Ex Works (EXW), Carriage And Insurance Paid To (CIP), and Free On Board (FOB)—are incorporated into sales contracts worldwide to define the responsibilities of buyers and sellers and to stipulate how costs and risks are to be divided. EXW, CIP, and FOB are incorporated into sales contracts worldwide; they define the responsibilities of buyers and sellers, and they stipulate how shipping costs and risks will be divided. Therefore, when buyers and sellers discuss a price, they must always stipulate which Incoterm will apply. If the price is agreed to on an *EXW* basis, it means that the buyer must pay separately for freight and handling costs. If the same price is agreed to be a *CIP*, it means that freight and handling costs are included in the price under discussion; thus, the seller will pay in due time.

The International Chamber of Commerce (ICC) publishes Incoterms; the United Nations recognizes them as clearly defining the most common terms used in international trade.

Incoterms are updated regularly; purchase contracts must reference the applicable version. The information in this manual is based on Incoterms 2010.

See annexure 1 for additional details, including a table that summarizes the responsibilities of the sellers and purchasers.

J. Letters of Credit and Other Payment Options

Letters of Credit are banking instruments commonly used in international trade; they have advantages for both the Buyer and the Seller:

- The sellers are assured that they will receive prompt payment.

- The buyers are assured that they can enforce contract conditions, such as quality requirements and shipping dates.

See annexure 2 for basic information about a letter of credit (L/C). See annexure 3 and the ICC publication Uniform Customs and Practice for Documentary Credits for other payment options. The Government of Khyber Pakhtunkhwa, however, may not want to open an irrevocable L/C to pay for contraceptives purchased under international competitive bidding procedures.

K. Specifications

Detailed technical specifications are critical to successful procurement because they provide potential suppliers with an accurate and complete picture of what is required. They are written in the technical vocabulary of the relevant industry and precisely describe characteristics and performance requirements of the goods to be purchased. They are "product neutral"; that is, they do not refer to brand names or catalogue numbers and describe requirements generically. If there are alternative sets of standard accessories to select from, the specifications clearly indicate choices. Under the bidding format used by both Government of Khyber Pakhtunkhwa and World Bank, the purchasing entity is responsible for providing technical specifications. Later, the formal specifications will become part of the contract between the supplier and the purchaser. Specifications are discussed further in Module I and in Module II. In addition, The Standard Bidding Documents for Procurement of Contraceptives, located at Appendix IV of this Manual, provides detailed guidance on contraceptive specifications.

L. Timeline for Procurement

Public sector procurement by ICB does not happen quickly. Twelve months or more may be needed for activities of the procurement office, evaluation committees, approval, and time periods for manufacturing and shipping. This timeline must also allow an additional two to four months for normal government budgeting and planning (operational plans, annual procurement plans); therefore, it could be 14–18 months from the time a need is identified; to the time goods are received, inspected, and released for use.

Of course, all procurements do not take 14–18 months; there are many variables; including, but not limited to (1) procedures and approvals in force at different financial thresholds; (2) supply issues, such as marketplace shortages; (3) technical issues, such as availability of detailed specifications; and (4) QA issues for pharmaceutical products in Pakistan.

See module 1 for additional information about procurement timelines.

M. Code of Ethics

The Government of Khyber Pakhtunkhwa also promotes a business code of ethics for the professional behavior of personnel engaged in procurement and contracting activities. This code is based upon the Khyber Pakhtunkhwa Public Procurement Regulatory Authority Act, 2012, clause 16 –Ethics and *Rule 5 of PPR 2014*.

See annexure 4 for a copy of the Code of Business Ethics and Integrity Pact.

N. Conflict of Interest

Although "Conflict of Interest" is not explained in Khyber Pakhtunkhwa Public Procurement Regulatory Authority Act, 2012, and *PPR 2014*, the generally accepted principles are:

> *(i) where a contractor, supplier or consultant provides, or could provide, or could be perceived as providing biased professional advice to a procuring agency to obtain an undue benefit for himself or those affiliated with him;*

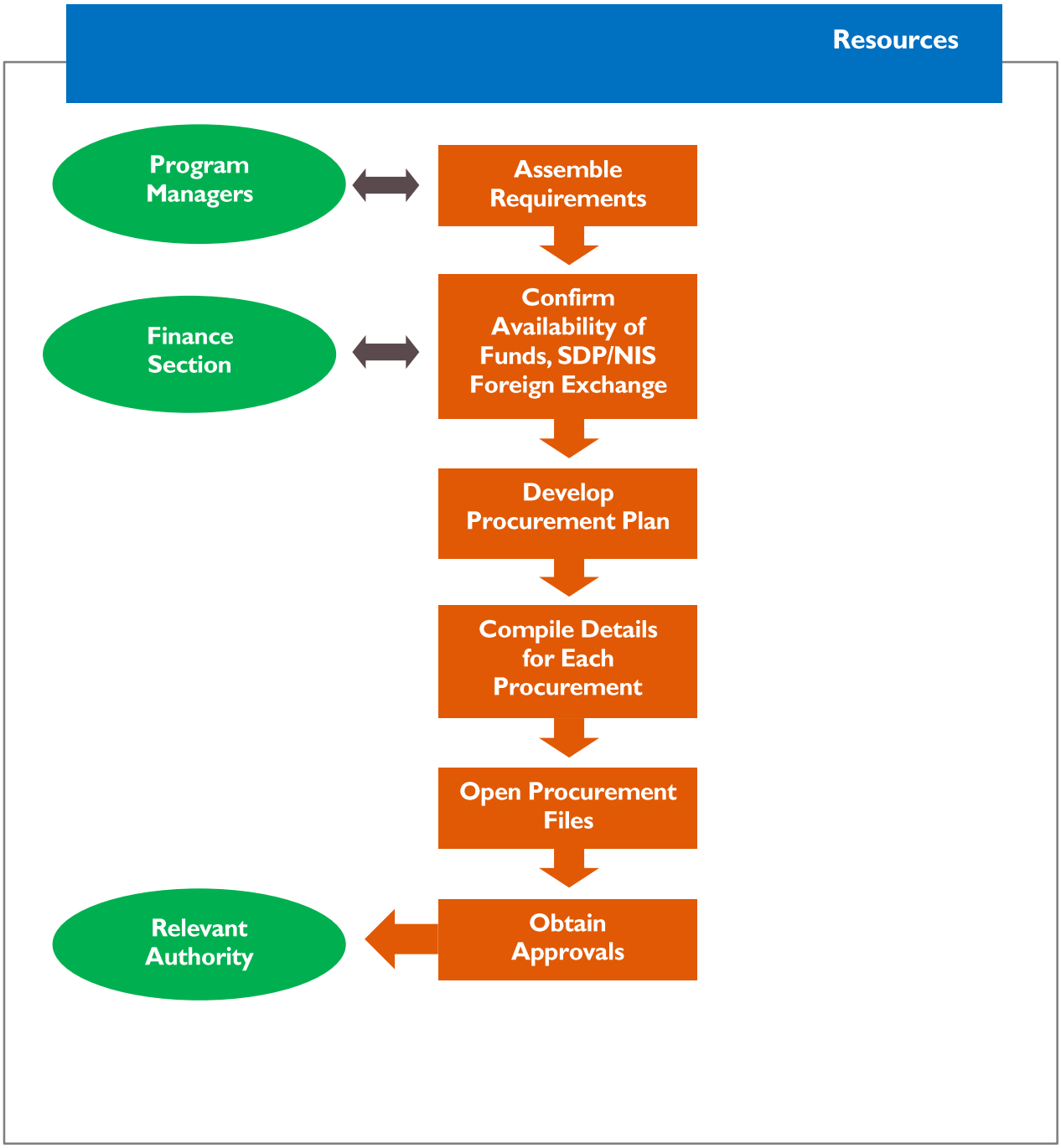
(ii) receiving or giving any remuneration directly or indirectly in connection with the assignment except as provided in the contract;

(iii) any engagement in consulting or other procurement activities of a contractor, consultant or service provider that conflicts with his role or relationship with the procuring agency under the contract;

(iv) where an official of the procuring agency engaged in the procurement process has a financial or economic interest in the outcome of the process of procurement, in a direct or an indirect manner;

Any conflict of interest that has been identified should be properly addressed according to applicable national and provincial laws.

Module 1: Planning and Preparation



Module I

A. Procurement Planning

B. Preparation for Procurement

A. Procurement Planning

Because of the extended timeframe associated with competitive public sector procurement, realistic planning is very important. It is especially critical for healthcare commodities, such as contraceptives—oral pills, injectable, condoms, etc.—because stockouts of these items may result in unwanted pregnancies. *Rule 30 of PPR 2014* states—

Each procuring entity shall plan its procurements with due consideration to transparency, economy, efficiency and timelines, and shall ensure equal opportunities to all prospective bidders in accordance with Clause 22 of PPRA Act 2012.

1. Budget Process and Operational Plan

Beginning in January of each year, program managers are asked to review their program goals and activities for the coming fiscal year (FY) (1 July–30 June). They need to consider probable resources (budget) and estimates for contraceptives, equipment, and services that will need to be purchased. These plans and estimates are submitted to the respective departments, where changes may be made, if required. The resulting operational plans and budgets are consolidated and forwarded to the government for approval.

After the annual operational plans are refined and approved by the government, program managers are responsible for communicating their approved requirements—usually in a completed procurement requisition—to the appropriate procuring units; the plans must include basic specifications and cost estimates that are within their approved budgets.

Two important factors help decide the amounts needed, per year, for procuring contraceptives:

1. An estimate of use based on population data and other factors; trained specialists may be needed to help with this step.
2. An account of how much stock is on hand; and how much has been ordered, but not yet delivered.

However, sometimes contraceptives can be purchased in quantities determined by budget availability; therefore, resupply calculations would not be relevant.

2. Procurement Plan

Obviously, every requirement cannot be processed at one time; therefore, procurement plans are developed that include tentative, package-wise schedules for purchasing activities. See annexure 5 for an example. As mentioned in the basics module, procurement plans include a broad description of the contraceptives to be purchased, including a budget amount and source, a time period for procuring the contraceptives, and the method of procurement.

The Government of Khyber Pakhtunkhwa uses procurement plans to organize annual revenue expenditures for goods and services.

3. Confirm Availability of Funds

Before a specific procurement plan is developed for a contraceptive procurement, it is important to confirm with the appropriate finance section that adequate funds and, if needed, foreign exchange are available to support the procurement.

4. Process for Developing an Annual Procurement Plan

The following process is used to develop an annual procurement plan.

4.1 Gather Information

The assigned procurement unit should receive procurement information early in the year to allow sufficient time for processing and procuring the requirement.

However, when procurement information is not provided within a reasonable time, it may be necessary to directly contact the party responsible for generating the information; the required information could include a specified deadline.

1. Send a letter to all users to submit their requirement for contraceptives for the next FY, by a specified deadline.
2. Send a reminder letter to users who do not respond within 25 days; also, send a copy to the next higher-level office, stating that the requirements must be submitted by the specified deadline.
3. Prepare a list of users who did not submit their requirements by the final deadline.
4. Send a letter to the people who are late, and send a copy to the next higher-level offices stating that the named users who failed to submit their requirements by the final deadline will not be included in the procurement plan for the following year; and no requirement will be accepted later.

4.2 Begin Filling out the Procurement Plan

Using the sample format shown in annexure 5, the procurement unit(s) should begin filling out the procurement plan.

1. Describe the contraceptives and enter the unit and quantities required.
2. Show the estimated cost of the contraceptives and the source of funds for each procurement
3. Enter the procurement method—for example, International Competitive Bidding (ICB). *Procurement Basics,* the first section in this manual, contains detailed information on procurement methods. See annexure 6 for a chart showing the financial threshold limits for different types of procurement.
4. Indicate the contract approving authority for each procurement, per the financial thresholds.

4.3 Estimate Timeframes and Complete the Procurement Plan

To estimate a timeframe for any single procurement activity, it is necessary to understand the procurement steps involved, level of approving authority required, time limits set by government regulation, and basic marketplace issues for the contraceptives being procured.

Annexure 7 shows an example timeline for procurement, assuming it is a high-value contract and a high-level approving authority.

a. Considering that procurement work needs to be sequenced—not all procurement is done at the same time—insert dates for advertising the bid, bid opening, bid evaluation, approval to award, notification of award, signing of contract, and completion of contract.
b. Add the total days and enter that number in the last column—*Total Time (in days)*.

B. Preparation for Procurement

1. Analyze Procurement Requirements

The procurement unit(s) must review requirements received from programs, which are often a procurement requisition. Analyze their needs in terms of—

- type of contraceptive method
- estimated quantity and cost of the contraceptives
- potential sources of contraceptives
- prior review requirements, etc.
- type of supply available—i.e., after production, off-the-shelf, or from wide range of market, etc.
- estimated lead time for delivery
- previous frequency of purchase.

At times, the procurement unit may need to prepare a procurement requisition. See annexure 8 for a sample procurement requisition form. See annexure 9 for information on preparing a procurement requisition form.

2. Open Procurement File

The procurement unit will need to open one set of files for each procurement activity in the approved procurement plan. Each procurement file must contain the appropriate procurement records, as required under *Rule 52 of PPR 2014*. Annexure 10 lists the records that can be considered for inclusion in the procurement file.

The procurement process, from planning to delivery of goods, can be completed in 12–18 months. All pertinent records and documents should be placed in the appropriate file for easy reference. By the time the procurement action is complete, each file (or set of files) will contain a record of the entire procurement action, from the planning stage to the completion of contractual liabilities. It is recommended that each procurement record contain the following files:

- signed procurement requisition
- product specifications
- budget estimate
- procurement plan and summary
- bidders list
- pre-qualification document
- record of advertisement
- bidding documents
- bid security documentation
- record of pre-bid conference
- modifications to bidding documents

- proposals from suppliers
- record of bid opening
- record of bid examination
- bid review committee summary
- award letter
- performance guarantee documentation
- signed contract
- bidder notification
- authorization for shipment
- shipping documents
- receiving report
- miscellaneous correspondence.

3. Procurement Records - Retention

Rule 52 of PPR 2014 requires procuring entities to preserve records and documents that relate to their public procurement for a minimum period of five years from the date the supplier finally discharges its contractual obligations. In special cases, records may need to be kept for a longer period; for instance, for development projects.

4. Summary Description of Planned Procurement

To guide the development of bidding documents and specifications, the procurement unit should write a *summary description* for each planned procurement. An experienced procurement officer or a technical specialist should be assigned to gather any missing information. The summary description includes—

- description and function of the contraceptive in enough detail for development of a technical specification
- unit of measure—each, kilograms, or pounds, cycles, gross, tubes, vials, unit packs, etc.
- quantity
- confirmed budget
- procurement method
- date needed
- final destination—within Khyber Pakhtunkhwa, usually the Central Warehouse
- requesting program manager, or other entity and date of request
- shipping terms—CIP, EXW, etc.
- payment terms—cash in advance, down payment, L/C, etc.
- name and address of consignee
- project identification numbers
- procurement approval date
- special requirements for contract—including QA testing
- special marking requirements for shipping boxes
- list of approvals required
- source of funds
- notes about special features of the goods, programs they will be used for, or the overall market situation.

Newly hired procurement staff will need to ask for help from more experienced officers about shipping and payment terms[1] to be used for the procurement package.

The technical specification committee, or other assigned technical experts, may need to be consulted about any special contract wording in addition to the technical specifications and schedule of requirements. In some cases, this information will not be available until the document development phase.

5. Development of Technical Specifications

Writing formal specifications requires a good understanding of the contraceptive to be purchased and working knowledge of the technical vocabulary used in the relevant industry. Thus, technical experts are often needed to help translate program managers' approved requirements into technical specifications that will give an accurate and complete picture of what is required of potential suppliers. The specification must comply with *PPR 2014*.

Early in the procurement process, technical consultants or other personnel may need to ask program managers to provide more information, or to make certain decisions about their requirements. As soon as possible, information gathered from the end-users should be compiled into formal procurement specifications for use in the draft bidding documents.

Appendix 4 contains sample technical specifications for contraceptives—oral contraceptives, injectable, intrauterine device (IUDs), condoms, and implants—that can be used for procurement.

6. Obtain Approvals

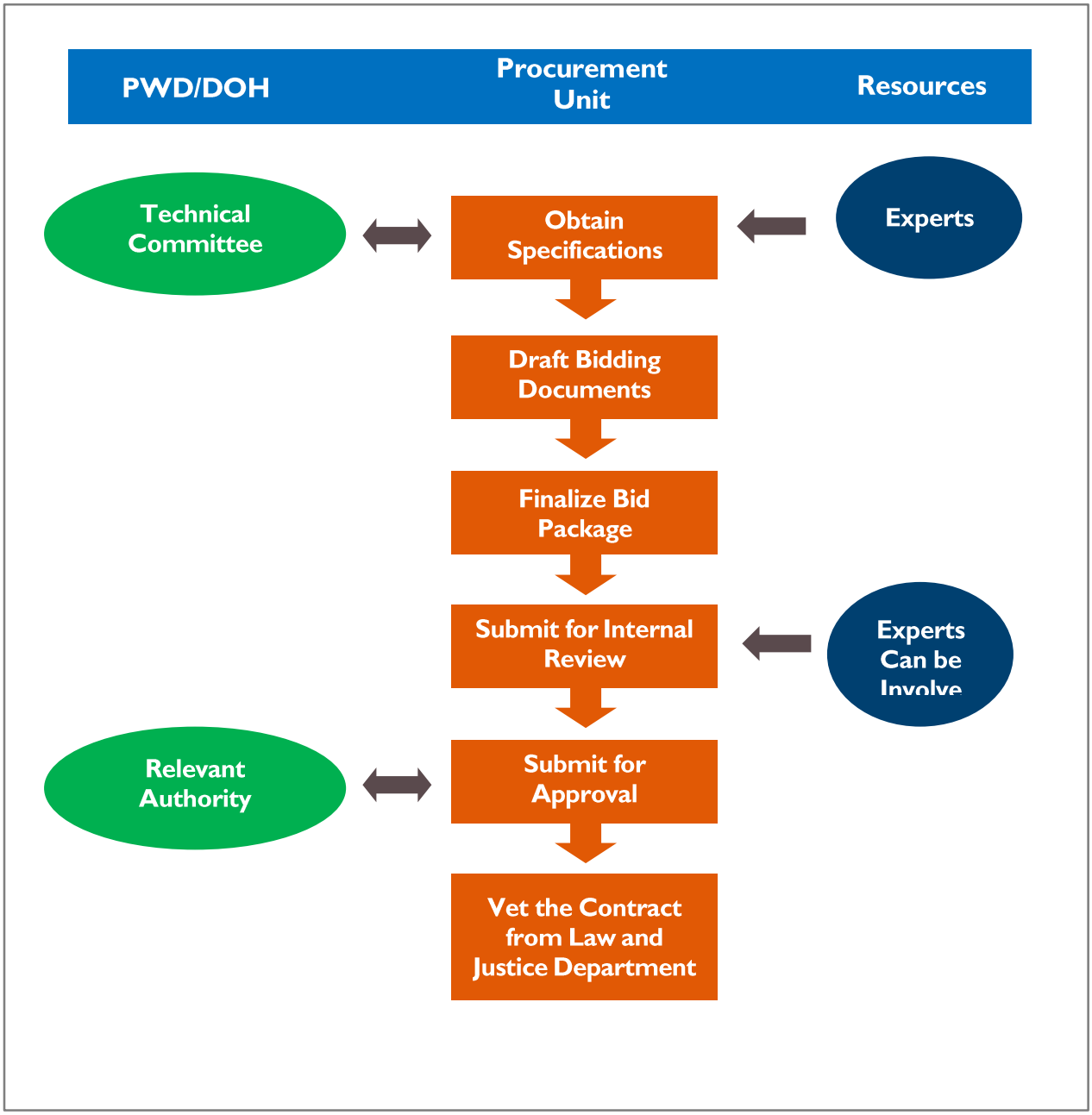
Approval by the relevant authority of the procurement plan constitutes administrative and financial approval for—

- procurement of the goods included in the plan
- method of procurement
- time schedule for procurement, as shown in the procurement plan
- office, cell, or other entity that will do the purchasing
- prior approval requirements.

7. Overview of Procurement Steps and Documents

Each procurement activity will follow a sequence of activity and will require specific documents, based on the method of procurement. See annexure 11 for a table of procurement steps and documents to be used as a reference tool for new procurement staff; it will help them visualize the steps that may be required to conduct a high-value contraceptive procurement. It also includes a framework for what is to come in modules 2–5.

Module 2: Standard Bidding Documents



Module 2

This section includes—

A. Introduction

B. Description of Standard Bidding Documents

C. Process for Preparing Documents for Procurement

A. Introduction

In public procurement, detailed bidding documents are either sold or given to potential suppliers. These documents state all the requirements about what is to be supplied and all the rules and procedures for bidding; they also announce the specific criteria that will be used to select a winning bid. Some sections will become part of the future contract between the supplier and the purchaser. Every aspect of these documents must be correct and complete.

Under the PPRA Act 2012 clause 23(1) "A procuring entity shall adopt standard bidding documents designed under this Act and insert/add specifications into the SBD for each, procurement." Clause 23(11) states "No change in the substance of bids, including changes in price, shall be sought, offered or permitted after the date and time of bid closing, except as otherwise provided for in the rules."

Careful drafting of the bidding documents is the key to preventing problems during bidding, evaluation, and contract performance.

This manual includes bidding documents that support the international procurement of contraceptives. They have been modified in line with the World Bank's S*tandard Bidding Documents Procurement of Health Sector Goods - International Competitive Bidding (May 2004)*. These documents will be used for both international, as well as national, competitive bidding procurement of contraceptives and condoms, after necessary adaptation. See appendix 3 for the World Bank document.

B. Description of Standard Bidding Documents

In the SBDs, several sections must be used unchanged, while the purchaser can change other sections. See the beginning of appendix 4 for an overview of the SBDs. The SBD includes guidance notes and instructions for the procuring agency. Procuring agencies will delete the notes, instructions, and unused options when they prepare documents for sale to potential bidders.

Each section of the SBD has a separate function:

1. Invitation for Bids (IFB)

The IFB is a copy of the advertisement or notification announcing the opportunity to bid; it includes relevant and essential information to help bidders decide whether or not to participate. It precedes the sale of the bidding document; it is for information only. The content must be consistent with the bid data sheet and the special conditions of contract. See annexure 12 for a sample IFB form.

2. Instructions to Bidders (ITB)

The ITB gives information to bidders for preparing and submitting their bids; it also explains the rules and procedures for—

- bid submission

- bid opening
- bid evaluation
- award of the contract
- definitions and warnings about fraud and corruption.

This section must be included in bidding documents *as is,* no changes can be made to the wording. (Information specific to the bid package is supplied through corresponding clauses in the Bid Data Sheet in the next section of the SBD.) See appendix 4 for a sample of instructions for the bidders form, including notes.

3. Bid Data Sheet (BDS)

The BDS provides information specific to the procurement action. The procuring agency uses this section to supplement and/or modify the instructions for bidders. It includes, but is not limited to—

- amount and type of bid security, if required
- directions for submitting bids, including markings and timeframe
- dates, times, and other specific information about bid opening
- specific criteria that will be used to evaluate bids, including any factors, other than price, that will be applied
- criteria for eligibility of contraceptives, and the particular documents required to establish eligibility and conformity to bidding documents
- criteria for eligibility and qualification of bidders, and the particular documents required to establish the bidder's eligibility and qualification
- specific information about awarding the contract

See appendix 4 for a sample BDS.

4. Ineligible Bidders

Lists of firms that are excluded from bidding on specific contracts under *Rule 44 of PPR, 2014* are on the Khyber Pakhtunkhwa Public Procurement Regulatory Authority website (if available) or department-owned website. International agencies—the World Bank, USAID, United Nations Children's Fund (UNICEF), United Nations Population Fund (UNFPA), World Health Organization (WHO), and Asian Development Bank (ADB), and others—also maintain lists of firms that are ineligible from bidding on their contracts because they violated the fraud and corruption provisions. The procurement unit may not enter into any contract with these firms.

5. General Conditions of Contract (GCC)

These widely used clauses will apply to the future contract. This section must be included in the bidding documents *as is,* without changing any of the wording. *General Conditions* cover standard, normal contract issues, such as—

- delivery
- payments
- warranty
- termination
- force majeure
- governing language
- notices.

Changes and additions are made through the SCC. See appendix 4 for a sample of a general SCC.

6. Special Conditions of Contract (SCC)

This includes clauses for the contract, specific to the procurement action. The procuring agency uses this section to supplement and/or modify like-numbered clauses in the *GCC*. Special conditions apply to unique procurement requirements, such as—

- requirement for immediate notification of air shipments
- regulatory compliance issues
- pre-shipment inspection and testing—critical for condom procurement
- any unacceptable trans-shipment points.

See appendix 4 for a sample SCC.

7. Technical Specifications (to be prepared by purchaser's technical expert)

These are precise technical descriptions of the goods to be supplied. The procuring agency inserts the specification—usually prepared by a technical expert—into the SBDs.

Technical specifications are one of the most important parts of procurement. They are the benchmarks against which the purchaser will verify the technical responsiveness of bids; and, subsequently, will evaluate the bids. The technical specifications must be in line with *Rule 33 of PPR 2014*. They must include a complete description of the product, written in industry-standard vocabulary and format, including, but not limited to—

- technical and performance characteristics
- size, units, quantity, and intended use
- packaging, packing, and marking
- regulatory requirements
- applicable standards and required certifications
- QA criteria, including detailed tests required
- acceptance criteria
- detailed activities to be performed by the supplier, if required
- list of detailed functional guarantees covered by the warranty.

Note:

Review the additional guidance note on technical specifications for contraceptives in appendix 4.

8. Schedule of Requirements

List the contraceptives and the required delivery schedules. The procuring agency fills out a form provided in the SBD that specifies the—

- procurement plan number
- named items required for purchase
- quantities
- delivery schedule
- place of delivery
- special notes.

See appendix 4 for a sample schedule of requirements form.

9. Evaluation and Qualification Criteria

The purchasing unit (PU) announces the criteria in the SBD (*Rules 33, PPR 2014*) that will be used to determine the lowest evaluated bid, and the bidder's qualification requirements. Qualification criteria usually include, but are not limited to—

- Financial capability in terms of average annual turnover during each of the past three years, as shown by audited financial statements.
- Experience and technical capacity demonstrated by the number of years manufacturing and/or selling the contraceptives to be supplied; completed similar contracts, including contact information for verification and bank references.
- Where applicable, licensing and registration by the Drugs Regulatory Authority of Pakistan (DRAP). See annexure 13 for detailed information about evaluation and qualification criteria for bidders.

10. Bid Submission

a. Bid Submission Form

To be completed and signed by the bidder:

- The signed bid submission form binds the successful bidder, including the conditions set out in the bidding documents; it becomes a temporary contract after the award is announced.

See appendix 4 for a sample bid submission form.

b. Price Schedule

To be completed and signed by the bidder:

- Itemized charges for the unit price of goods, domestic value added (as per policy of government), freight, and insurance.
- To calculate a margin of preference for locally manufactured products—as per the government policy—separates foreign and domestic bidders.

See appendix 4 for sample price schedule forms for contraceptives manufactured inside and outside Pakistan.

c. Manufacturer's Authorization Letter

To be completed and signed by the manufacturer of goods, if the bidder is not the manufacturer:

- Authorizes named party (bidder) to submit a bid
- Confirms warranty obligation.

See appendix 4 for a sample of the manufacturer's authorization letter.

d. Bid Security Form

To be filled in and signed by guarantor (bank), or used as an example for a document on the guarantor's letterhead.

- Guarantor's undertaking to pay a specified amount (not below 1 percent and not exceeding 5 percent of the bid prices), if the bidder receives an award but fails to go forward with a contract.

See appendix 4 for sample bid security forms.

e. Contract Agreement Form

To be signed by purchaser and winning bidder:

- Incorporates relevant sections of bid documents into a binding contract.
  - GCC
  - Special Conditions of Contract
  - Technical Specification and Schedule of Requirements
  - supplier's bid and original price schedules
  - purchaser's notification of award
  - any other documents specified by purchaser.

See appendix 4 for a sample contract agreement form.

f. Performance Security Form

To be filled in and signed by the guarantor (bank), or used as example for the document on the guarantor's letterhead.

- Guarantor's undertaking to pay specified amount (not to exceed 10 percent of contract price) if awarded bidder defaults on the contract.

See appendix 4 for a sample performance security form.

g. Bank Guarantee for Advance Payments

To be filled in and signed by the guarantor (bank), or used as example for a document on the guarantor's letterhead.

- Guarantor's undertaking to pay a specified amount if the supplier uses advance payment for any purpose other than for delivery of the goods.

See appendix 4 for a sample bank guarantee for advance payment form.

h. Certificate of Pharmaceutical Product

To be provided by manufacturer of pharmaceutical contraceptive:

- This establishes the status of a pharmaceutical product moving in international commerce and of the applicant for the certificate, with regard to certifications, licensing, and marketing.
- Part of a scheme developed by WHO to combat the sale and distribution of sub-standard and/or counterfeit pharmaceutical products.

See appendix 4 for a sample certificate of pharmaceutical product form.

C. Steps for Developing Draft Bidding Documents

All but three sections of the standard bidding documents must be filled out with information specific to the current procurement. The sections that are to be filled out include—

- BDS
- Special Conditions of Contract
- evaluation and qualification criteria
- schedule of requirements
- technical specifications.

Additionally, it will be necessary to develop an IFB with information that matches the data sheet and special conditions of contract, after they have been developed.

The treatment of a particular topic must be consistent from section to section of the bidding documents; and extreme care must be taken to avoid language that contradicts, overlaps, or duplicates wording in another section.

The procurement unit will need to look for information in the draft bidding documents and act as a coordination point for integrating different sections. Some of the required information will be available from the approved procurement plan; preparations will be made at the early stages of procurement. For additional information, refer to the summary description of the planned procurement that was developed as described in module 1, section B.4.

1. Select and Study the Standard Bidding Documents

Procurement staff and managers should select the standard bidding document that best suits the requirements and the procurement method approved in the procurement plan. They should thoroughly study each section of the selected document. This preparation will help to ensure that the bidding document draft is well-prepared, consistent from section to section, and covers all the information needed for bid evaluation. In addition, it will provide a good understanding of how the procurement process is expected to proceed and the rules that must be followed.

The procurement unit must look for and identify any problems that might occur during bidding, evaluation, and contract performance; and try to design the bidding document clauses to prevent problems, as much as possible.

Instead of working on the document sections in their established order, it is more efficient to start in the middle and work on several at the same time. Develop the technical specifications and the schedule of requirements first, because they are the *bones* of the procurement, around which everything else will be built.

2. Obtain Technical Specifications

Qualified experts should write and submit to the procurement unit detailed technical specifications. Technical specifications include different things, depending on the type of product to be purchased:

For pharmaceutical contraceptive procurement—

- chemical and pharmacological attributes
- quality and safety issues
- shelf life
- presentation (primary packaging)
- pre-shipment inspection (and possibly testing)
- labeling.

For condom procurement—

- dimensions
- packaging
- shelf life
- pre-shipment inspection and testing
- standards.

2.1 If the specifications offered are inappropriate, based on the information above and the examples

in appendix 4, contact the responsible party, technical consultant, and/or specification committee (if there is one) for clarification and any necessary revision.

2.2 Use the detailed specifications to guide development of all remaining bidding document components.

3. Prepare Schedule of Requirements

3.1 Review the procurement plan and summary description of planned procurement before working on the schedule of requirements.

3.2 Remove the schedule of requirements section from the applicable set of standard bidding documents and look at it carefully.

3.3 Read the guidance notes and fill out the schedule of requirements as follows:

a. **Procurement plan**: Insert a sequential number to identify the procurement plan.
b. **Description**: Write a short description of the contraceptives available in appendix 4—just enough to clearly identify the product. (The technical specifications will have a more detailed description.)
c. **Quantity**: Enter the total quantity that will be purchased under the contract. Do not mention partial shipment amounts.
d. Delivery schedule: Establish the date when the end user needs the contraceptives, then carefully calculate a *delivery date,* taking into account the implications of Incoterms, such as CIP, that will apply to the procurement contract. In many cases, the contraceptives are considered delivered as soon as they are handed over to the carrier—without waiting until they reach their final destination. If this is the case, for the contraceptives to arrive in Pakistan by the due date, the calculation for *delivery date* should allow for transit and clearing time. The delivery date can be a specific month, day, and year; or a number of weeks after a stated event, such as after confirmation of a L/C. This is where it is indicated that the product will be delivered in partial shipments, and to outline the required schedule.
e. Mode of shipment: Enter air, ocean, truck, etc.
f. Point of delivery: For international procurement, usually determined by the Incoterm, as noted above.
g. Special notes: Additional information, explanations, or qualifications can be added at the bottom of the form.

4. Begin Drafting the Bid Data Sheet

The function of the BDS is to modify and augment information and requirements printed in the Instructions to Bidders (ITB). Text in the ITB mentions the DBS whenever specific information or requirements are needed to complete the instructions. All DBS clauses are numbered to match corresponding, or *mother* clauses in the ITB.

4.1 Read and understand clause(s) in ITB that corresponds to the required DBS information. This is *very* important because the DBS wording itself is not intuitive; that is, it is difficult to understand what it means without referring to the *mother* clause. This will help to ensure that time is not wasted pursuing the wrong answers.

4.2 Consider whether ITB and standard data sheet clauses will adequately represent the procurement to be undertaken. Additional clauses can be included, if they do not contradict the standard instructions to bidders (ITB) or the *PPR, 2014*.

4.3 Fill in all known information; for example, the name of the purchaser.

4.4 List the information still needed to complete the DBS (referenced by clause number).

4.5 Consider where/ how to locate the missing information; for example, program decision, earlier bidding document, line director, calculation, consultant, specification.

4.6 Pursue and coordinate required decisions; for example:

- price of bidding documents
- amounts of bid security
- amount of performance guarantee
- if samples are required
- date and time for pre-bid meeting, if required
- bid opening date and time, bid validity requirement
- if bids will be accepted for less than the full quantity
- if the price should be quoted as fixed
- if domestic preference will be applied
- if the evaluation will be based on items or lots
- bid currency and bid language.

5. Specify Eligibility Criteria and Documents Required

In accordance with *Rule 41 of PPR, 2014*, all interested bidders, national or international, firms and individuals, shall be allowed to bid for any project where international competitive bidding is adopted. However, competition may be restricted if, as a matter of law, the bidder prohibits country commercial relations; or a firm is blacklisted or debarred by the procuring agency and the matter has been reported to the KPPR Authority, in accordance with *Rule 44 of PPR, 2014*. Eligibility requirements are primarily based on whether or not a firm has been blacklisted.

5.1 Determine and list any criteria on the BDS for eligibility, in addition to those already mentioned in the ITB.

5.2 For the health sector documents, use appropriate wording for the DBS, clauses 6.3 and 6.4, about procurement-specific documentation of conformity with bidding documents and registration with the DRAP.

5.3 Give bidders contact information so they can obtain additional information about requirements for registering contraceptives.

6. Specify Evaluation Criteria and Documents Required

6.1 Determine the criteria that will be used to evaluate and compare bids—in addition to what has already been mentioned in the ITB—and list it on the BDS. This will relate primarily to price adjustments and the application of economic factors.

Examples include—

- domestic preference (as per the policy of government)
- cross discounts
- efficiency factors
- possibility of early delivery.

6.2 If criteria are used, in addition to price, insert the information for the bidder on how non-financial items will be evaluated.

6.3 In the examples above, also mention the possibility of early delivery in the Schedule of Requirements.

7. Specify Qualification Criteria and Documents Required for Evidence

SBDs for contraceptives procurement require four basic bidder qualifications:

1. The manufacturer must have adequate production capacity and experience.
2. The manufacturer must have verifiable technical capability.
3. The bidder must have verifiable business and financial stability.
4. The bidder must have a history of successful performance.

It is at the discretion of the procuring agency to develop *specific criteria* that will be used to decide whether or not a bidder is qualified for a contract award. For example, for production capacity, the procuring agency would define exactly how much capacity it considers *adequate,* based on quantity and delivery time requirements of the subject procurement, including the documentary evidence the bidder should submit.

7.1 Determine for each of the four basic qualification criteria above, the specific criteria that will be required.

Guidance notes in the standard bidding documents offer assistance for designing appropriate qualification clauses. Qualification criteria for contraceptives include QA elements.

7.2 Determine and list documentary evidence that bidders should submit to establish (or confirm) their qualifications.

Defining evidence to support specific criteria is not as straightforward as defining the requirement itself. The purchaser might ask the bidder for a sworn statement of its installed manufacturing capacity; and peak and average production, during the past three years. But, on evaluation, other details and documents submitted with the bid will be used to corroborate the bidder's claims. The firm's financial information and audited financial statements, details of current commitments, contracts completed over the past several years, and the bidder's explicit permission for the purchaser to contact business and banking references will all be considered.

See annexure 46 for additional information to consider for qualifying bidders.

8. Specify Any Addition Document Comprising the Bid

The ITB specifies the documents that will comprise the bid, but it also allows the procuring agency to include more documents in this list, through the respective BDS.

9. Bid Data Sheet Completion

Enter the products from steps 4–8 into the appropriate clauses of the BDS. Ensure that all guidance notes and unused options are deleted. This is frequently overlooked and causes confusion about what exactly is required.

10. Begin Drafting Special Conditions of Contract (SCC)

SCCs modify and augment information and requirements printed in the GCC. Whenever specific information or requirements are needed in the SCC to complete the contract conditions, it is noted in the text of the GCC the same way the ITB and BDS were cross-referenced.

10.1 Read and understand the clause(s) in the appropriate version of GCC corresponding to the

special conditions requiring completion. This is very important because the wording of the special conditions is not intuitive; that is, it is difficult to determine what they mean without referring to the mother clauses. This will help ensure that time is not wasted pursuing the wrong answers.

10.2 Consider whether the GCC and standard SCC clauses will adequately represent the procurement contract that is desired. Additional clauses can be included, if they do not contradict the standard GCC clauses or the prevailing procurement regulations and guidelines.

10.3 Fill in all known information; for example, the nature of contraceptives to be supplied, purchaser's name and address, etc.

10.4 List the information and decisions that are still needed to complete the SCC/PCC (referenced by clause number).

10.5 Consider possible sources of any missing information. For example, from any authority at the provincial- and district-level; earlier bidding document; consultant; specifications; DRAP; PPR 2014, PPRA Act, 2012; and so on.

10.6 Pursue and coordinate necessary decisions, for example—

- documents that will be part of the contract
- packing, marking, documentation requirements
- method and conditions of payment
- inspections and tests required.

10.7 List the resources and capabilities that will be needed during the execution of the contract. For example, inspection agents, insurance surveyors, testing facilities, customs clearing services, banking and L/C facilities, etc.

10.8 Collect information about the local import practices, procedures, and requirements. For example—

- import licensing
- dockside sampling program
- currency exchange regulations
- customs tariff and taxes
- pro forma invoice
- product registration
- documentation
- L/C procedures.

Note:
Confirm that the L/C capability has been arranged with a registered bank in Pakistan.

10.9 Take steps to correct deficiencies in resources and capabilities that will be needed during procurement and contract performance. In particular, pay attention to international services, such as testing laboratories and pre-shipment inspection services. In a few cases, research the local practices and capabilities, which will reveal problems. For example, inspection agents need to be appointed and/or L/C arrangements may need to be set-up in order to refine the future contract. The procurement unit should begin any required processes as soon as possible, to ensure that delays will not occur when the services are needed.

11. Enter Specifics for Certification of Goods Clause

Pharmaceutical contraceptives require registration with the Drugs Regulatory Authority, Government of Pakistan (GOP) (where required); contracts, generally, cannot become effective until this has been completed.

SCC 6.1 asks for details of registration. SCC 6.2 provides wording if contraceptives have already been registered or registration is not required. SCC 6.3 displays the limit on how much time can lapse before the contract will be considered null and void.

Note:

Under the Drug Act of 1976, the procuring entity cannot sign the contract until the pharmaceutical contraceptives are registered in Pakistan. It is critically important for the procurement unit to know the registration status and to monitor progress, because the drug regulatory procedures can delay contract signing and the contraceptive delivery date**.**

12. Enter Specifics for Inspections and Tests Clauses

12.1 Note inspections and tests that will be applicable to the contract:

- pre-shipment compliance by supplier
- pre-shipment compliance by purchaser
- general dockside sampling and inspection—government import program
- acceptance testing in Pakistan.

12.2 Specify inspections and/or tests not otherwise mentioned in the standard documents; provide a cross-reference to the corresponding requirements in the Schedule of Requirements and Technical Specifications.

Pre-shipment inspection and sampling is conducted at the manufacturer's facility; testing, if required, is done at an independent laboratory before shipment. Select an independent laboratory that meets all the international standards prescribed by WHO for testing of contraceptives should be—known as a *pre-shipment compliance program*. It may include all or part of the following:

- documentary review
- inspection at the manufacturer's facility
- sampling
- testing at an independent laboratory.

Pre-shipment compliance programs ensure that only safe and good quality products reach the end user; they can also eliminate the time and trouble of returning contraceptives, and waiting for another shipment, if a sub-standard or incorrect contraceptives are detected.

When the timely receipt of contraceptives is critical to program operations, pre-shipment compliance programs are very important. See appendix 7 for more information.

13. Enter Specifics for Packing, Marking and Package Documents Clauses

List the requirements that, in addition to the GCC text, provide a cross-reference to corresponding requirements in the Schedule of Requirements and Technical Specifications. For example, you may want certain information printed on the outside of the packing boxes to facilitate warehousing and

distribution, or there may be a requirement to pack medicines in a specific way to ensure they remain below a certain temperature; for example, with vaccines.

14. Enter Specifics for Shipping and Other Documents to be furnished by Supplier

Determine and list shipping documents that will be required, including—

- commercial invoice
- air waybill
- clean on-board bill of lading (B/L)*
- packing list
- Certificate of Analysis.

The procurement unit should identify any other documents that may be required for shipping and provided by the manufacturer, including customs clearance for specific items.

** Particular care should be taken with specifying the clean on-board B/L.*

Note:
If the L/C requires the seller to present the original, negotiable B/L to a specific bank for payment, the contract clause about shipping documents should not require the seller to send it—the original, negotiable B/L—to the purchaser with other advance shipping documents. (The purchaser receives the B/L from the commercial bank after the supplier is paid. See information on Letters of Credit in the Basics module.)

14.1 Determine and list the documents that will be required to establish the product's conformity to basic specifications. (Also mention the required items in the corresponding specification.) For example—

- certificate of analysis
- QA records.

14.2 State the number of originals and the number of copies required for each document.

15. Complete the Remaining SCC Clauses

Ensure that all required entries have been made and that the treatment of each issue in Special Conditions is consistent with the wording in the corresponding BDS, Schedule of Requirements and Technical Specification.

16. Construct the Invitation for Bids

Using information in the completed BDS, SCC, and Specifications and Schedule of Requirements, prepare the IFBS by following the format and directions provided in the SDB. See annexure 12 for a sample invitation to bid form.

17. Compile Draft Bidding Documents Package

The bidding documents must be compiled in accordance with *Rule 33 of PPR, 2014*. Some of the sections/information that will remain part of the bidding document include—

- IFB
- Instructions to Bidders
- BDS
- GCC
- SCC
- schedule of requirements
- technical specifications
- eligibility for provision of goods
- forms to be filled out, referenced, or used by the bidder (Bid Form, Price Sheet, Bid Security, etc.).

Apply page numbering and develop a table of contents and a title page.

18. Prepare Bidding Documents Fact Sheet

A fact sheet for the bidding documents should contain an *at-a-glance* overview of important information about the package, including—

- short description of the contraceptives
- estimated cost and quantity of the contraceptives
- procurement method
- if prior review is, or is not, required
- requesting agency (end user)

See annexure 14 for a sample fact sheet on the bidding document form.

19. Prepare Prospective Bidders' List

The procurement unit will develop a list of suppliers that may be able to provide the required contraceptives. This list can be used for ICB when direct invitations will be issued instead of, or in addition to, advertising.

Sources for potential suppliers include—

- responders to general procurement notice
- prior marketing knowledge
- national and international registers and publications
- international nongovernmental organizations
- foreign embassies
- chambers of commerce
- donors and United Nations agencies
- firms previously enlisted by the government
- firms pre-qualified by an earlier formal process

20. Submit Draft Bidding Documents for Internal Review

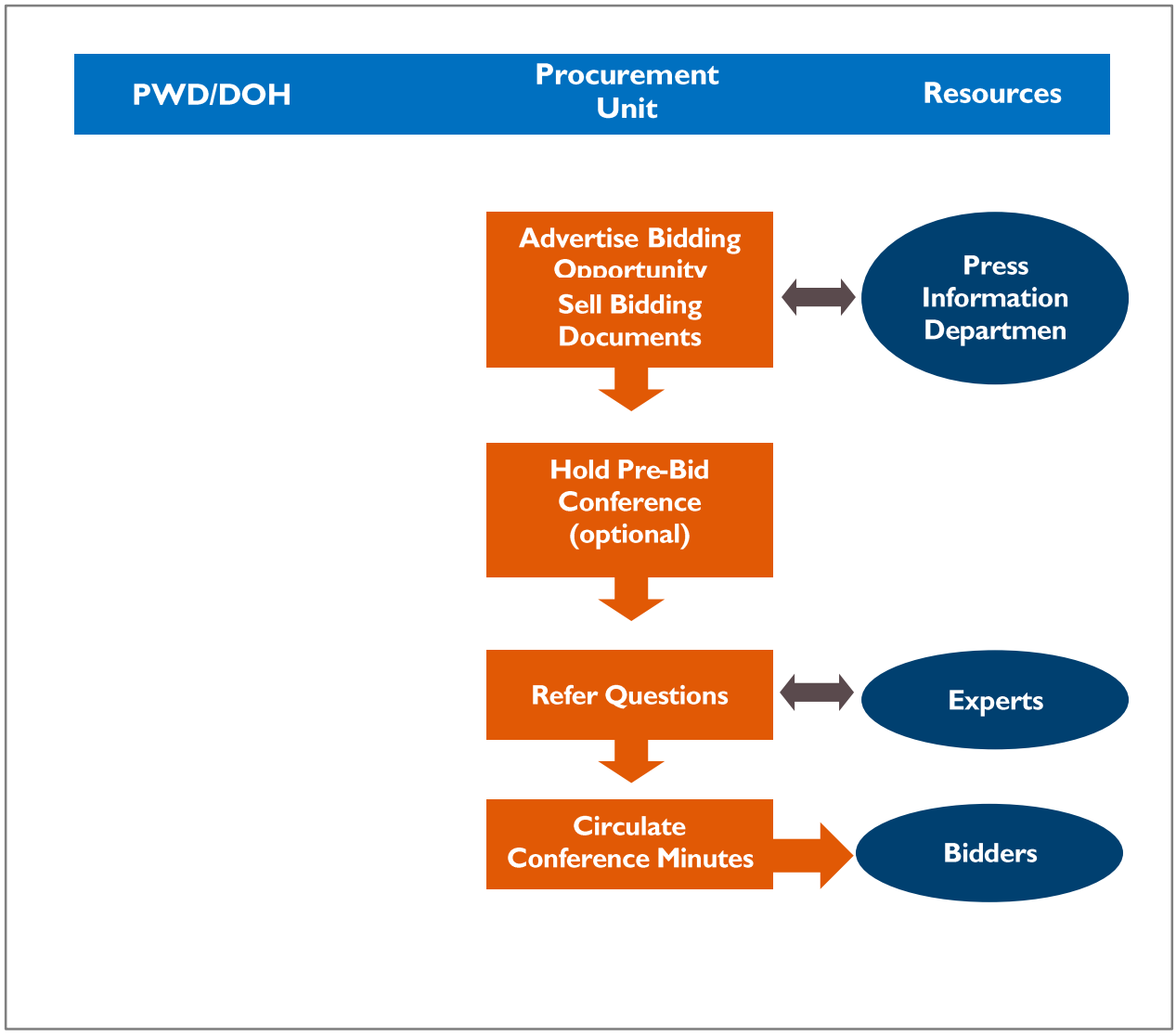
Send draft copies of the bid package and fact sheet to the responsible parties within or outside the department—if local expertise is not available.

They should—

- check the draft against the procurement plan
- verify authenticity of the requirement of the contraceptives
- investigate any other relevant factors

- ensure the technical specifications are accurate and include appropriate detail
- ensure that any evaluation criteria, in addition to price, are clearly stated and appropriate for program needs
- endorse (approve) the draft bidding documents for onward disposal, with or without revision.

Module 3: Invitation and Receipt of Bids



Module 3

This section includes—

A. Steps for Inviting Bids

B. Pre-Bid Conference.

A. Steps for Inviting Bids

1. Advertise the Opportunity to Participate in Bidding

As soon as the relevant authority approves the draft bidding document, the procurement unit must advertise the opportunity for bidding. That is, it must extend a public invitation to all interested firms and parties to participate in the competition for a contract. This is one of the essential elements of *open competition*.

Procurements over 100,000 rupees and up to 2.5 million rupees will be advertised by timely notifications on the authority's website and, possibly, in print media using the manner and format prescribed in *Rule 11 of PPR 2014*.

All procurement opportunities over 2.5 million rupees shall be advertised on the authority's website, as well as in the newspapers as prescribed under *Rule 11 of PPR 2014*.

For international competitive bidding, *Rule 41 of PPR 2014*requires that the procurement opportunity be published in print media or newspapers with a wide circulation, as well as on the PPRA website, concerned departments, and any international advertisement sources. Print media advertisements should be placed in at least two widely circulated leading dailies in English and Urdu languages. See annexure 15 for a sample format for advertising an international competitive bid.

1.1 Prepare a version of the invitation for bids that is suitable for newspapers and periodical publications.

1.2 Using the format identified in annexure 15, prepare a version of the invitation for bids that is suitable for website publication. Use the following instructions to submit the advertisement and use the facilities provided on the appropriate website.

1.3 For international competitive procurement, also place advertisements in appropriate international journals, publications, and websites; for example, http://www.dgmarket.com. The World Bank's health sector bidding documents suggest *SCRIP - World Pharmaceutical News*.

1.4 Post notices at the procurement unit and on the official or public notice boards.

1.5 Inform all the Chambers of Commerce in Pakistan.

1.6 In the case of ICB, send notices to foreign embassies and trade missions in Pakistan.

2. Prepare Bidding Document Sets and a Document Register

Documents must be ready for issue or sale to interested parties at the time the advertisement appears; the bidding documents will be issued for at least 15 days for NCB and at least 30 days for ICB (*Rule 34 of PPR, 2014*).

2.1 Determine the number of bidding document sets that should be produced for sale, based on—

- type of goods to be purchased
- approximate number of prospective bidders—for example, a small number for contraceptives
- source of goods—national or international
- previous sale of bidding documents for similar goods.

2.2 Determine the number of bidding document sets needed for official departmental purposes.

2.3 Prepare sets (copies) of the bidding documents.

2.4 *All* procuring agencies will display the bidding documents on the website of the authority and the procuring agency, in case the procuring agency has its own website. The bidders can submit bids on the bidding documents issues by the procuring agency or download them from the authority's website, with the tender fee, if any, by mail or by hand.

2.5 Set up a register to record all the bidding document sets prepared for the package. Number the documents so that each set can be accounted for when the bidding process is complete.

3. Prepare Systems for Safeguarding Bids, Cash and Securities

3.1 Set aside a secure location to hold the bids, unopened, until the stated day and time of bid opening; for example, in a locked cabinet.

3.2 Set up a system for managing the funds collected from the prospective bidders for the cost of the bidding documents.

3.3 Set up a system for safeguarding securities after bids have been opened.

4. Set-up Procedure for Transmitting Bidding Documents to Prospective Bidders Outside of Pakistan

4.1 Select the methods—mail, courier, or express document service.

4.2 Arrange capacity for paying postage or courier fees.

5. Availability of Bidding Documents to Bidders

5.1 The procurement unit should make the bidding documents available for international procurement. The price should be minimal and should only reflect the cost of printing and providing the documents.

5.2 Use the register mentioned in 2.4 to record the name and address, and document the number of each purchaser so they can stay informed about any pre-bid conferences, amendments to the documents, or other official business.

5.3 Use the register in 2.4 to record the name and address, and document the number of the sets forwarded to official sources at no cost.

5.4 Provide receipts to bidders with name, address, date, and time the bidder received the bidding documents.

B. Pre-Bid Conference (Optional)

Pre-bid conferences for prospective suppliers are held for international and important local procurements, whenever necessary (*Rule-37(10) of PPR 2014*). At a pre-bid conference, potential

bidders' questions are answered and minutes are recorded and sent to each recipient of the original bidding documents in sufficient time for bidders to take appropriate actions before the deadline for the receipt of bids.

In a competitive situation, these conferences can become difficult to control. Therefore, it is very important to set a firm agenda and plan in advance for managing the flow of questions and answers. Bidding documents may need to be amended as a result of questions and issues that registered participants bring up. Procedural errors during the conference, or in writing or distributing the minutes, can result in official protests by competing bidders. Any protest is likely to delay the procurement.

1. Arrange the Pre-Bid Conference

Any pre-bid conference should take place well before the bid opening date. The concerned director should determine a convenient place and time for the conference. The room must be large enough to hold at least—

- two representatives from every intending and prospective bidder
- all officers and directors with a major role in developing or approving the draft bidding documents; these individuals can be organized into a bidding document finalization committee
- appropriate procurement unit staff and their director(s).

2. Notify Prospective Bidders

Notify the prospective bidders about the conference when they purchase the bidding documents. All prospective bidders should receive this notice, including the last bidder to purchase them before the pre-bid conference.

3. Hold the Pre-Bid Conference

3.1 Register participants and generate an attendance list, including titles and contact information. *Limit attendance to parties who purchased bidding documents.*

3.2 Record the minutes following the sample in annexure 16.

3.3 Immediately refer questions and concerns that cannot be answered at the conference to technical experts. See annexure 17 for a sample reference letter.

3.4 Use the sample format in annexure 18 to forward replies (per 3.3) to registered participants and all registered bidders as soon as they are received.

3.5 If necessary, extend the bid submission period and/or amend the bidding documents, based on the answer to the questions asked during the pre-bid conference.

4. Circulate the Minutes and/or Outcome of Pre-bid Conference

Note

All parties who have purchased bidding documents must receive exactly the same information.

4.1 Send the minutes and other related information to all prospective bidders, including those who purchased bidding documents *after* the pre-bid conference.

4.2 Send a copy of the conference minutes to the end user office.

5. Extend the Bid Submission Deadline if Necessary

5.1 Notify prospective bidders if the bid submission deadline is extended. See annexure 19 for a sample format for notification.

5.2 The advertisement of an extension shall be made in time and manner similar to the original advertisement.

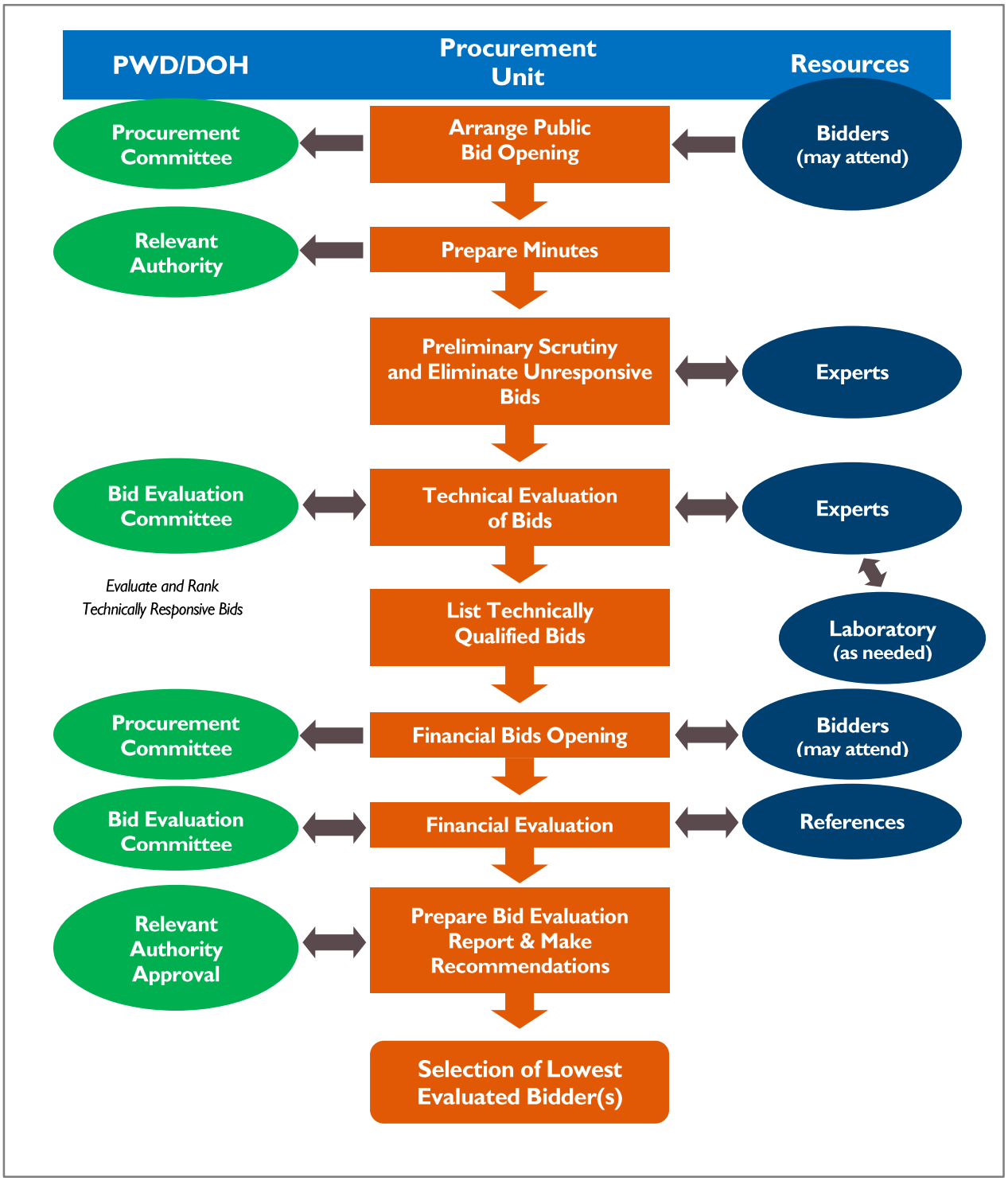
6. Receiving and Managing Bids

6.1 If bids are received by courier, mail, in person, etc., within the time limit specified in the IFB, they must be held unopened until the stated day and time of bid opening. The bids can be deposited in a safe box under safe custody of the PU.

6.2 Stamp bid envelopes with the date and time they are received.

6.3 Except for questions and answers in writing to/from procurement, no one associated with the procurement is permitted to communicate with bidders about the bid from the time the advertisement appears until after an award has been made.

Module 4: Bid Opening, Evaluation, and Selection



Module 4:

This section includes—

A. Introduction
B. Steps for Bid Opening
C. Bid Evaluation Format
D. Steps for Organizing the Bid Evaluation Process
E. Steps for Technical Evaluation of Bids
F. Steps for Financial Evaluation
G. Steps for Verifying Bid Securities
H. Steps for Qualifying Lowest Evaluated Bidder
I. Assembling the Contract
J. Recommending for Award
K. Approvals and Authorization
L. Announcement of Evaluation Reports
M. Extension of Bid Validity
N. Redressed of Grievances.

A. Introduction

The procedure described in this manual is based on the single-stage two-envelope bidding process, which is commonly adopted for procurement of goods under *Rule 6 (2) (b) of PPR, 2014* for goods over the value of Rs. 100,000. The rule states—

"Single stage, two envelops procedure.-- this method shall be used where bids are to be evaluated on technical and financial grounds and price is taken into account after technical evaluation. Bid shall comprise a single package containing separate envelopes. Each envelope shall contain separately the financial proposal and technical proposal."

The bid opening, evaluation, and selection of a winning bidder is governed by *Rules 37to 45of PPR 2014*.

B. Steps for Bid Opening (single-stage two-envelope method)

Bids must be opened publicly for both local and international procurements at the time stated in the bidding documents. Bidders can attend the opening, but it is not mandatory. Bid opening procedures should follow *Rules 37to 45of PPR 2014*.

1. Organize the Bid Opening (officers of procuring agency)

1.1 At least seven days before the bid opening, use the format in annexure 21 to notify members of the procurement committee (PC).

1.2 Arrange the place for bid opening, as specified in the bidding documents. Ensure that it is well-lighted, large enough to accommodate at least two people from each bidding firm, and has audio facilities, if required.

1.3 Hold all bids unopened and secure until the date and hour designated in the bidding documents.

2. Record Bid Submissions (officers of procuring agency)

As the bids arrive—

2.1 Provide receipts.

2.2 Record the bidder name and the submission date. (Bids received after the exact deadline will not be opened.)

3. Hold Bid Opening (procurement committee)

On the date, and at the time and place specified on the bidding documents—

3.1 Admit the participants—

- authorized bidders
- others directly involved with the subject procurement; for example, consultants hired for the purpose.

3.2 Require each attendee to register on an attendance sheet provided for that purpose, and include—

- name and address
- company, manufacturer, representative
- organizational affiliation (if not bidder)
- signature.

Ensure that a member of the PC countersigns the attendance sheet.

3.3 Open all bids received before the deadline, one at a time, and read the bid aloud:

- bidder's name and local agent's name, if different
- bidder's city/state or province/country
- withdrawal or modifications, if any
- quoted items.

Hold all financial bid envelopes unopened in a box—to be opened at a later date, after the technical evaluation.

3.4 Record all samples received. Record any samples received with the bid on a record of samples received form. See annexure 22 for a sample form.

3.5 Do not open bids received after the deadline for the receipt of bids Return these bids to the bidder unopened.

4. Record and Distribute Details (PC)

4.1 As each bid is read, complete a bid opening checklist (see annexure 23). At this stage, if the bid was received on time, it cannot be eliminated, even if something appears to be missing or incorrect.

4.2 Record the details of the bid on a Bid Opening Sheet (BOS), or record of bid opening similar to annexure 24.

4.3 Require all members of the PC, and the bidders, or their representatives who attend the bid opening, to sign the BOS after the opening is complete.

The steps above summarize the key activities to be performed during the bid opening. See annexure 25 for additional detailed guidance on opening bids.

Note:

After the public bid opening and report, have no further contact with bidders until the winner is identified

and notified. No meetings or conversations can be held between the purchaser and bidders during the evaluation process. C. Bid Evaluation Format

C. Bid Evaluation Format

PPR, 2014 does not define a specific evaluation procedure, or offer a step-by-step format, for selecting a winning bid; but, it does require a bid comparison sheet, a recommendation for award, and an evaluation report.

The World Bank's Standard Bid Evaluation Forms (SBEF) conform to the provisions of *PPR, 2014*; the forms can be modified for use and guidance in evaluating bids. See annexure 20 for a table of contents for the forms. Step-by-step guidance for members of evaluation committee are given below:

SBEF Documents

The SBEF provides tables and forms that can be used to procure entities examine and evaluate each bid submission; and select the winning bid, based on a fair application of the rules, procedures, and requirements set down in the bidding documents. This module (4) will use the SBEF to explain the bid opening, evaluation, and award stages for contraceptive procurement, based on *Rule 6 (2)* single-stage two-envelope procedure.

D. Steps for Organizing the Evaluation Process

1. Fill out SBEF tables 1–3.

1.1 Fill out SBEF table 1, Identification (see annexure 27). It requires very basic information about the subject procurement package, most can be found in the approved procurement plan, including the original cost estimate. The remaining information is in the bidding document.

1.2 Fill out SBEF table 2, Bidding Process (see annexure 28) with basic information about the bidding process, including publication dates, title of bidding documents, and amendment dates.

1.3 Fill out SBEF table 3, Bid Submission and Opening (see annexure 29), with information about the bid submission and opening, including the deadline and opening dates, bid validity period, and number of bids received.

2. Check Copies and Secure Bid Originals

2.1 Compare each copy of each bid with its original and correct, if necessary.

2.2 Confirm that signatures on each original are present.

2.3 Keep originals in a safe location and use copies for evaluation work.

3. Complete the Bid Opening Checklist for Each Bid

3.1 Enter any incomplete information. For example, descriptions at bid opening may need to be explained in more detail.

3.2 Verify the information recorded at the bid opening.

4. Hold the financial bid envelopes unopened in a box; they will be opened at a later date, after the technical evaluation process.

E. Steps for Preliminary Examination of Bids

The examination outlined in SBEF table 4 (see annexure 30) is used to identify and reject bids that are incomplete, invalid, or substantially non-responsive to the bidding documents. Only bids that pass this phase can continue with the financial evaluation and be compared with the other bids.

1. Review Original Bidding Documents

To evaluate a bid, it is important to know *what* to evaluate; this information is in the original bidding documents.

1.1 Thoroughly review the original bidding document issued for the procurement.

1.2 Particularly, to understand what each bid should agree to or offer, note the entries in the BDS and SCC, as well as the Schedule of Requirements.

2. Review Preliminary Examination Form (SBEF table 4)

SBEF table 4, a summary record, shows how each bid for a goods contract is substantially responsive or substantially non-responsive to the bidding documents. It includes columns for recording the bidder's name, verification of information, and eligibility of information, bid security information, completeness of bid, substantial responsiveness, and acceptance for detailed examination. Additional columns can be added, as necessary. In most cases, they will be required for responsiveness to technical specifications and commercial conditions.

To record details of each bid's responsiveness or non-responsiveness in that category, each column of table 4—except the bidder's name—must include at least one supplementary schedule or checklist. These supplementary schedules must reflect the exact requirements, terms, and conditions of the original bidding documents. The following sections discuss how to complete the supplementary schedules for SBEF table 4 columns.

3. Refer Bids for Technical Evaluation

Soon after the bids are opened, a technical expert, or a technical evaluation sub-committee, should examine the bids for technical content. Although it is not listed on the table 4 headings, the technical evaluation is a critical part of determining a bid's responsiveness to the requirements, and whether or not it can proceed to the next stage—financial evaluation and comparison.

3.1 Examine each bid for modifications, exceptions, and interlineations (notations written between the lines of the original bidding documents) regarding—

- Compliance with technical specifications provided in the bidding documents.
- Compliance with general and Special Conditions of Contract included in the bidding documents that are related to the technical specifications; for example, contract requirements for pre-shipment inspection, sampling, and testing.

3.2 List and cross-reference deviations from the bidding documents and indicate whether or not they are acceptable or unacceptable; include the reasons.

3.3 For each bid record, document the findings for compliance with technical specifications. See annexure 32 for a sample technical evaluation sub-schedule for recording technical evaluation

findings. A list of the actual technical specifications must be incorporated into this schedule. A scoring system, which gives points for different criteria, can be adopted; it must be mentioned in the bidding documents.

3.4 If bidders are required to submit samples for inspection and/or testing, it is the procurement unit's responsibility to facilitate arrangements for any necessary testing to be done at a qualified government testing laboratory, or at a pre-qualified independent testing laboratory, and obtain the written reports.

Note on Testing

Testing is sometimes restricted to samples from several prospective suppliers with the lowest substantially responsive bids, but may also be reserved for bids from new or previously unreliable suppliers. In this case, testing would be delayed until the financial evaluation is complete.

Testing samples submitted with bids are not appropriate for health sector goods, such as contraceptives, pharmaceuticals, and vaccines, because this will not assure the quality of *a product batch to be produced in the future.*

3.5 Summarize the findings and provide overall comments on the technical evaluation. See annexure 33 for a sample summary table for recording information about the technical evaluation. A list of the actual technical specifications must be incorporated into this schedule.

4. Undertake Verification Exercise: Table 4–column b

Annexure 34, a sample checklist for column b of table 4, is used to examine the details of the verification issues. Real bidding documents will include additional issues that must be examined during the verification exercise.

The PC should—

4.1 Review bidding documents for items to be checked in this category and prepare a checklist.

4.2 Examine all bids and note deficiencies that, if accepted, would be an unfair advantage to other bidders. Significant judgment must be used. For example, simple omissions or mistakes resulting from human error should not be grounds for rejecting the bid. However, the validity of the bid itself, for example, its signature, must not be in question.

4.3 Do not consider any information contained in a bid submission that was not specifically requested in the bidding document.

5. Assess Eligibility of Bidder: Table 4–column c

Annexure 35 is a sample checklist for examining the details of eligibility issues. Real bidding documents will include additional issues that should be addressed during the eligibility examination.

The Bid Evaluation Committee (BEC) should—

5.1 Review the bidding documents for items to be checked in this category; prepare a list.

5.2 Check the KPPRA website, or any other reliable website, for a list of debarred firms.

5.3 Confirm the eligibility of each bidder and the goods offered.

- If pre-qualification is complete, only bids from pre-qualified bidders can be considered.

- A bidder can be disqualified if the government puts it on a debarment list.

6. Examine Bids for Completeness: Table 4–column d

Annexure 37 is a sample checklist for column d of SBEF table 4, which is used to record details about the completeness of the bid. Real bidding documents will include additional issues that should be addressed during the bid completeness examination.

6.1 Review bidding documents for items to be checked in this category; prepare a list.

6.2 Review the bids and note if any are incomplete or deviate from the original documents.

- Unless the bidding documents specifically allow bidders to quote for select items only, or for only partial quantities of an item, bids not offering all the required items (both type and quantity) will ordinarily be considered non-responsive. This decision requires *significant judgment.*
- Changes or additions to the bidding document by the bidder are usually treated as deviations, but they may be acceptable if they are corrective, editorial, or explanatory. This also requires *significant judgment.*

7. Examine Bids for Commercial Responsiveness (sub-schedule for table 4–column e)

Annexure 38 is a sample sub-schedule for column e of SBEF table 5 used to exam the details of commercial responsiveness. Real bidding documents may include additional issues that should be addressed during the commercial responsiveness examination. Deviations that are specified in the bidding documents—Instructions to Bidders section—that require rejection of the bid, must be listed.

8. Obtain and Review Technical Evaluation Report

The technical expert, or committee, indicates whether or not the bid is technically acceptable (see annexures 32 and 33). The bid committee notes this determination in its evaluation report.

9. Identify Substantially Responsive Bids: Table 4–column e

9.1 Review the technical evaluation report and the findings from the other sub-schedule evaluations of SBEF table 4 and determine if each bid is substantially responsive to the requirement terms and conditions stated in the bidding documents.

Note

This step requires significant judgment and extreme care. The procuring entity may regard a bid as responsive, even if it contains minor deviations.

Bids that are determined to be "not substantially responsive" cannot be considered further (in other words, they will not be evaluated on the basis of price). Major deviations from the commercial requirements (8 above) and technical specifications (9 above) are a basis for the rejection of bids. Bidders are not allowed to correct or withdraw material deviations or reservations after bids have been opened.

Definitions

A bid is considered *substantially responsive* when it is presented in the required manner and appears to include all required information, samples, statements, securities, signatures, forms and supporting documentation, and contains no material deviations from or reservations to the terms, conditions, and

specifications in the bidding documents.

A *material deviation* is a significant and unacceptable difference from the requirements stated in the bidding documents. As a general rule, major (or material) deviations are those that, if accepted, would not fulfill the purposes for which the bid is requested, or would prevent a fair comparison with bids that are properly compliant with the bidding documents.

A material (or major) deviation affects the price, quantity, quality, or delivery of the goods as required in the bid documents, or limits the responsibilities, duties, or liabilities of the bidder, or any rights of the purchaser.

However, bids that offer deviations may be considered substantially responsive—at least for fairness—if the deviations can be assigned a monetary value that would be added as a penalty during the financial evaluation process; and, if such deviations would be acceptable in the eventual contract.

10. Accept Bids for Financial Examination (table 4–column f)

10.1 List each bid and indicate whether it will be accepted for financial evaluation, based on the results of their technical evaluation and approval from the relevant authority. If a bid fails acceptance, the reasons must be clearly explained in footnotes or in an attachment. The table 4 column number and schedule where the bid fails to meet requirements should be indicated.

This determination requires significant judgment and extreme care. Bids that are judged "substantially non-responsive" must be rejected without further consideration.

10.2 After the evaluation and approval of the technical proposal, the procuring agency, at a time during the bid validity period, will publicly open the financial proposals of the technically accepted bids only. The financial proposal of bids found technically non-responsive will be returned to the respective bidders unopened.

After the technical evaluation, the financial proposals of bidders that are eligible for the financial evaluation are opened publicly at a separate bid opening meeting, at a date and time made known to the bidders whose technical proposals have been evaluated and accepted. Total prices quoted are read aloud and recorded, including all the itemized unit prices, with the technical scores, awarded to bidders in the technical evaluation.

F. Steps for Financial Evaluation (SBEF table 5–11)

For each bid that passes the technical evaluation stage, the PC must arrive at an *evaluated cost*. SBEF tables 5–11 help ensure a fair comparison among all the technically qualified bidders. Subject to post-qualification, the bid with the lowest *evaluated cost*, ***but not necessarily the lowest submitted price***, must be chosen for award.

The "evaluated cost" is not necessarily the submitted price; it takes corrections, discounts and other factors into consideration and gives them a value. Bidding documents must list factors to be considered, in addition to price, and describe the manner in which they will be applied.

1. Complete SBEF table 5—Bid Prices as Read-Out (see annexure 31).

2. Calculate corrections and unconditional discounts (see SBEF table 6).

The PC should use table 6 (see annexure 39) to incorporate corrections and unconditional discounts in the calculation for an evaluated cost.

2.1 **Corrections for errors:** For each bid, multiply the unit price by the quantity. If the sum does not match the total or sub-total in the bid, enter the difference as a plus or minus in column d. In other words, the stated unit price prevails. If there is a discrepancy between words and figures, the amount in words prevail. Corrections are considered binding on the bidder. The PU can call the bidders for verification of corrections. Explain in footnotes unusual or substantial corrections that could affect the comparative ranking of bids.

2.2 **Corrections for provisional sums:** Sometimes the bidding documents ask bidders to include provisional sums for contingencies. These sums are the same for all bids and they must be entered as a minus in column e to ensure a fair comparison of bids.

2.3 **Modifications and unconditional discounts:** Bidders are allowed to modify their bids before the deadline for submission. These modifications can include either increases or discounts to the bid amounts that reflect last-minute business decisions. Enter any modification or unconditional discount that is not reflected in the read-out bid price into columns g and h.

2.4 **Corrected/discounted bid price(s):** Table 6, column I, shows how to calculate this important figure. Cross discounts are not yet included. They are calculated after all other evaluation steps are completed.

3. Fill out exchange rate (SBEF table 7) (see annexure 40)

3.1 Check the original bidding documents (ITB); for comparison, enter the currency specified.

3.2 Attach a copy of the exchange rates provided by the specified authority or publication (usually, The State Bank of Pakistan) to table 7.

In the next step, the corrected/discounted bid prices will be converted to a common evaluation currency.

4. Calculate currency conversion—multiple currencies (SBEF table 8) (see annexure 41)

This table is used for goods. It calculates a total bid price in the specified evaluation currency using the exchange rate(s) in table 7.

5. Calculate additions, adjustments, and priced deviations (SBEF table 10) (see annexure 42)

5.1 **Additions:** Enter amounts from table 8 in *column b*. Omissions to the bid are then compensated for in *column c* by adding an estimated price; for example, syringes that are not included in the price of injectable contraceptives. Where items are missing in some bids but are present in others, use an average of the quoted prices. External sources, such as published price lists, freight tariff schedules, etc., are also appropriate. Express the addition in the evaluation currency.

5.2 **Adjustments:** The original bidding documents can specify performance or service factors (costs or savings), which will be considered in the evaluation, by assigning cash value to a non-cash factor. If these factors are going to be used, they will be explained in the data sheet section of the bidding documents. The methods used to evaluate these factors must be consistent with the data sheet provisions and must be described in the evaluation report. The value of adjustments are expressed in the evaluation currency and are shown in *column d*.

5.3 **Priced deviations:** Bids with minor deviations can be considered substantially responsive if a

monetary cost or penalty is assigned to the bid for bid comparison. Ignore vague statements by the bidder, such as "we wish to discuss changes in the delivery schedule." However, an explicit statement by a bidder, such as "we wish to extend the delivery date by 30 days," should be treated as a deviation. In this case, the time difference can be assigned a monetary value based on the rate of liquidated damages (L/D) specified in the bidding documents. Enter the penalty amount in *column e*, in the evaluation currency.

5.4 **Total price:** Enter the new total price in *column f*. Table 10 calculates the sum of *columns b*, *c, d*, and *e*. Take extra care in the calculation if any amounts in *column d* (or *e*) should be subtracted rather than added.

6. Calculate domestic preference for goods (SBEF table 11) (see annexure 43)

If goods from within Pakistan are not the lowest offer, table 11 calculates the margin of preference for offers of goods produced in Pakistan and applies it to the bid price of the foreign offers. The ITBs and BDS will indicate if a domestic preference is allowed, as per the policy of the government.

6.1 Divide the bids into three groups (group A, group B, and group C).

Group A: Bids exclusively offering goods manufactured in Pakistan, if labor, raw materials, and components amount to are more than 30 percent of the EX Works price of the product offered.

Group B: All other bids offering goods from within Pakistan.

Group C: Bids offering goods from abroad that have already been imported, or that will be directly imported (quoted on CIP basis).

6.2 Review the bid form and price schedules that the bidders submitted. Check each bid to make sure the bidder filled out the correct price schedule for the group classification (A, B, or C).

6.3 Determine the lowest bid in each group (A, B, and C) by comparing all bids in the group against each other; use the amount calculated in table 10, column f.

6.4 Compare the lowest bids from each group (A, B, and C); if a bid from group A or group B is the lowest, select it for the award.

6.5 If the lowest bid is from group C (foreign), compare it with the lowest bid from group A, after adding a premium to the bid price of the group C bid; follow the instructions below.

Column c—Total price: Enter the amounts calculated in table 10, column f.

Column d—Exclusions for preference: Enter the sum of the amounts calculated in table 10, *columns d* and *e,* plus other costs incurred within the purchaser's country. Add footnotes to explain the significant components of *column d*.

Column e—Revised total: Enter the amount of *column c,* minus *column d.*

Column f—Prevailing tariff (%): Ignore this column. It is no longer used.

Column g—Domestic preference (%): Enter 15%.

Column h—Preference price: For group C (foreign) bids, multiply the percentage in *column g* by the revised total in *column e*. For group A bids, enter *0* in *column h*. At this stage, do not consider group B bids.

Column i—Total comparison price: Add the amount in *column h* to the amount in *column c*

for each bid; enter the total in *column i*. This price will be used to establish the lowest *evaluated* bid.

6.6 If the group A bid is now the lowest, select it for the award. If not, select the lowest bid from group C.

7. Assemble summary ranking of financial evaluation

For clarity and convenience, develop a summary ranking of the financial evaluation of technically responsive bids; list the bidders and their total bid price. A revised schedule may be needed if domestic preference or cross discounts change the ranking. See annexure 44 for a sample ranking worksheet for financial evaluation.

8. Apply any cross discounts

These conditional discounts are offered when more than one contract or lot could be awarded to the same bidder. The BEC must select the best combination of awards, based on the lowest overall cost of the total contract package. Bid evaluation in these cases can be complicated, with many variations.

The cross discount worksheet (see annexure 45) shows an example of basic information and calculations needed to determine whether it would be less expensive to purchase a group of bid packages individually from each of the lowest evaluated bidders, or to purchase a group of bid packages from one bidder who offers a discount that is applied to the total.

Column a (first line): Enter name of bidder offering a conditional discount.

Column b (first line): List the bid packages that the bidder would discount in *column a* if all packages in the group were awarded to him. Include the package number and the price without the discount.

Column c (first line): Enter the discount offered by the bidder (usually a percentage).

Column d: Apply the discount in *column c* to each bid package price noted in *column b* to find a discounted price for each bid package. Next, calculate the sum of the discounted bid package prices and enter that amount on the first line of *column d*.

Column e: Starting on the second line in column a, list the lowest evaluated bidder for each separate bid package, the corresponding bid package number in *column b*, and the bid prices in *column e*. Next, calculate the sum of the lowest evaluated bid prices; enter the total on the first line of *column e*.

Column f: Indicate the lower of *column d* and *e*; include remarks.

If cross discounts were offered, include a copy of the cross discount worksheet in the bid evaluation report.

G. Steps for Verifying Bid Securities

Bid securities in a fixed amount (specified in the BDS) are submitted with financial bids from both local and international bidders. The bidding documents will state which form(s) of bid security will be accepted.

Generally accepted securities include—

- pay order
- bank draft

- bank guarantee.

No cash money is allowed.

Annexure 36 is a sample checklist used to exam the bid security details. Real bidding documents will include additional issues that should be addressed during the bid security examination. Review the bidding documents for items to be checked in this category and prepare a list. Ensure that all bid securities conform to the requirement stated in ITB.

1. Safeguard and record bid securities

1.1 Segregate the bid securities as soon as possible, after the financial bids are opened.

1.2 Hold the bid securities in a locked, secure location until a contract has been awarded.

1.3 Record each bid security in the register.

2. Confirm bid securities

Confirm the validity of all bid securities within 15 days after the financial bid opening.

2.1 Use any legal source to confirm the bid securities issued by banks within Pakistan (local issuing banks), preferably by speaking with a bank officer at the bank.

2.2 Confirm the bid securities issued by banks or other institutions outside Pakistan by email, fax, telegram, telex, letter, etc. See annexure 26 for a sample request letter that can be used.

2.3 Confirm the bid securities issued by banks outside Pakistan, but that has a correspondent bank within Pakistan. Use any legal source; preferably, by speaking with a bank officer at the correspondent bank.

H. Steps for Qualifying the Lowest Evaluated Bidder

If prequalification was conducted, the bidder whose bid is the *lowest evaluated* should receive the award, unless—

- The bidder's qualifications have materially deteriorated.

The purchaser must satisfy itself fully on the following accounts.

- Examine the updated information submitted by the *lowest evaluated* bidder and determine if it still meets the original prequalification criteria. Ask for clarification or updates from the bidder, as required.
- If the *lowest evaluated* bidder is still qualified, include this information in the evaluation report.

If prequalification was not done, the lowest evaluated bidder must be post-qualified using the requirements stated in the bidding documents.

1. Develop a bidder's qualification worksheet

1.1 To facilitate the qualification process, develop a bidder's qualification worksheet based on qualification criteria announced in the bidding documents. See annexure 46 for an example of the bidder qualification criteria that can be used as a worksheet.

1.2 Also, see module 2, section 7 of this manual.

2. Examine documents and statements

2.1 Examine the documents and statements provided by the bidder with regard to qualification criteria announced in the bidding documents.

2.2 Record the findings on the worksheet.

3. Check references

3.1 To verify statements and obtain information on past performance and financial standing, contact the references and institutions provided by the bidder.

4. Determine qualification status

4.1 Determine if the lowest evaluated bidder satisfies all the qualification criteria.

4.2 If the lowest evaluated bidder fails post-qualification, reject its bid; subject the next ranked bidder to the same post-qualification examination. If successful, this bidder should receive the award. If not, continue the process.

4.3 If a bidder fails post-qualification, clearly explain the justification and document it in attachments to the bid evaluation report. A history of poor performance can be considered adequate justification.

I. Assembling the Contract

The contract is important because, after it is signed, it becomes a legally binding document between the purchaser and the seller that identifies—

- product specifications
- delivery requirements
- performance obligations of both parties
- legal recourse for the parties involved, in case of lack of performance or disputes.

Contract preparation for international competitive bidding occurs during the process of developing the bidding documents; this is when the product specifications, delivery requirements, general and special contract conditions, and QA requirements specific to the contraceptive are assembled. While this can be a complex preparation process, the bidding documents provide the bidder with all the pertinent contract information and requirements so that, when the contract is awarded, the contract is basically in place and the winning bidder only has to sign the contract agreement form.

The documents that typically are included in the contract include—

- form of contract
- bid form and the price schedule submitted by the bidder
- schedule of requirements (offered by the bidder and accepted by the purchaser)
- the technical specifications (offered by the bidder and accepted by the purchaser)
- GCC
- SCC (filled in)
- Performance Security submitted by the bidder.

The purchaser should review the assembled contract documents to ensure that key requirements and contract provisions from the following categories are included in the contract, as needed:

- product requirements
- delivery requirements
- certification requirements
- inspection and testing rights
- payment terms
- special QA conditions appropriate to the commodity
- funder requirements (if required)
- warranty clauses
- termination clauses
- remedy clauses.

J. Recommending for Award

1. Prepare a bid evaluation report

1.1 The procurement committee prepares a bid evaluation report that includes documentation about the bid opening process, preliminary bid examination, technical evaluation, and financial evaluation. See annexure 47 for a sample bid evaluation report. Even if only one bid is submitted, the bidding process can be considered valid; if the bid was satisfactorily advertised and prices are reasonable, compared to market values, or the prices of the last awarded contract *(Rule 45 of PPR, 2014)*.

1.2 Attach notes of explanation for any extraordinary factors, such as prices higher than estimated, lower than expected, only one bid submitted, etc.

1.3 Recommend the evaluated, qualified bidder with the lowest evaluated price for the award.

1.4 Sign the evaluation report—each member must sign and clearly state their name and designation.

1.5 If any member of the BEC disagrees with the recommendation, a member can write a note of dissent describing their reasons, in detail.

2. Submit Report to the Approving Authority

2.1 Submit the evaluation report *(Rule 46 of PPR 2014)* with recommendations for award and note of dissent, if any, to the approving authority. See annexure 48 for a sample Request for Evaluation Report Approval form and annexure 49 for a Recommendation for Contract Award form.

K. Government Approvals and Authorization

1. The appropriate approving authority must formally approve the award recommendation (Rule 46, PPR 2014).

2. After reviewing the Bid Evaluation Report (BER) Summary, and confirming that the bid evaluation process was properly followed, and the award recommendation is consistent with a fair and equitable bid evaluation process; as documented by the BER Summary, the approving authority is responsible for promptly approving the award recommendation.

By promptly approving award recommendations, based on a fair and equitable bid evaluation process, the approving authority helps—

a. Increase the confidence of bidders in the procurement process, which encourages bidders to compete for Government of Khyber Pakhtunkhwa contracts; thereby, increasing competition

that can lead to reduced product prices.

b. Reduce the number of protests filed by bidders if they think the approving authority made an arbitrary decision that was not based on the bid evaluation process; and that, as a result, their bid did not receive fair and equal consideration, as required by *Rule 39 of PPR, 2014*.
c. To support the product delivery schedule, ensure that the contract is awarded to the manufacturer in a reasonable time.

3. If the approving authority determines that the bid evaluation process, as documented by the bid evaluation report summary, was not conducted in a fair and equitable manner, then it may—

a. ask for any clarification required from the bid evaluation committee
b. reject the recommendation, clearly documenting in writing the reasons for the rejection, and request a re-evaluation
c. reject the recommendations, clearly documenting, in writing, the reasons for the rejection; and issue instructions to reprocess the procurement, in accordance with the *Rule 48 of PPR 2014*.

4. The decision of the approving authority will be communicated to the procuring agency the same way the request for approval was initially submitted.

5. After the procuring agency receives the approval, the Notification of Award (NOA) for the procurement contract must be issued within 15 days, if no complaint or appeal is pending against the bidder.

L. Announcement of Evaluation Reports

Under *Rule 45 of PPR 2014*, at least seven days prior to awarding the procurement contract, the procuring agency must announce the results of the bid evaluation in a report that justifies the acceptance or rejection of bids.

M. Extending Bid Validity (if needed)

If justified by exceptional circumstances, a procuring entity can ask a bidder to extend the validity period of its bid (*Rule 35 of PPR 2014)* which shall not be more than the original period of the bid validity. Bidders are not required to agree to these requests. However, if a bidder agrees, it must be in writing and must confirm the new date for the expiry of bids requested by the procuring entity. If the bidder submitted bid security, the bid security must be extended, as well.

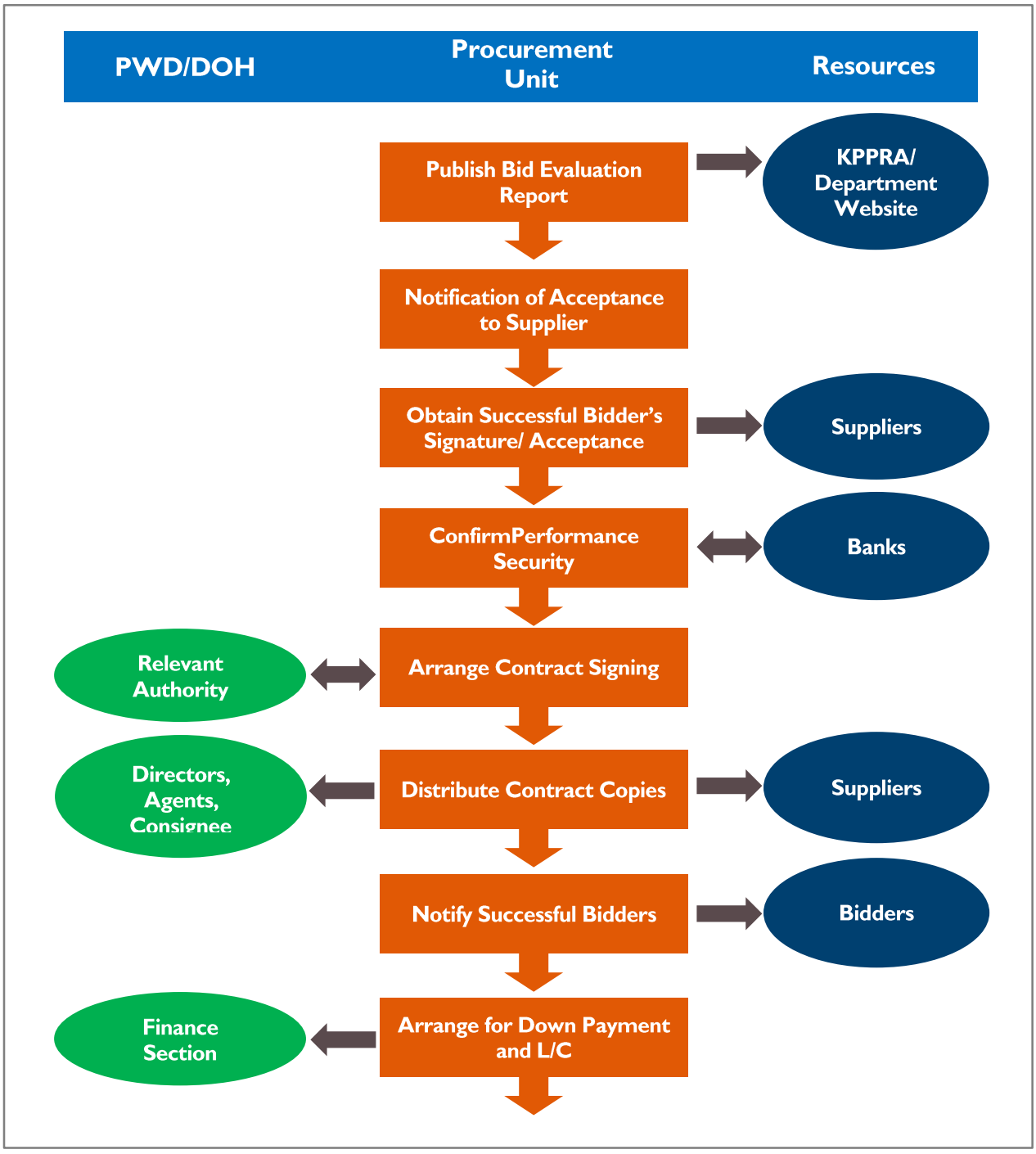
N. Redressal of Grievances

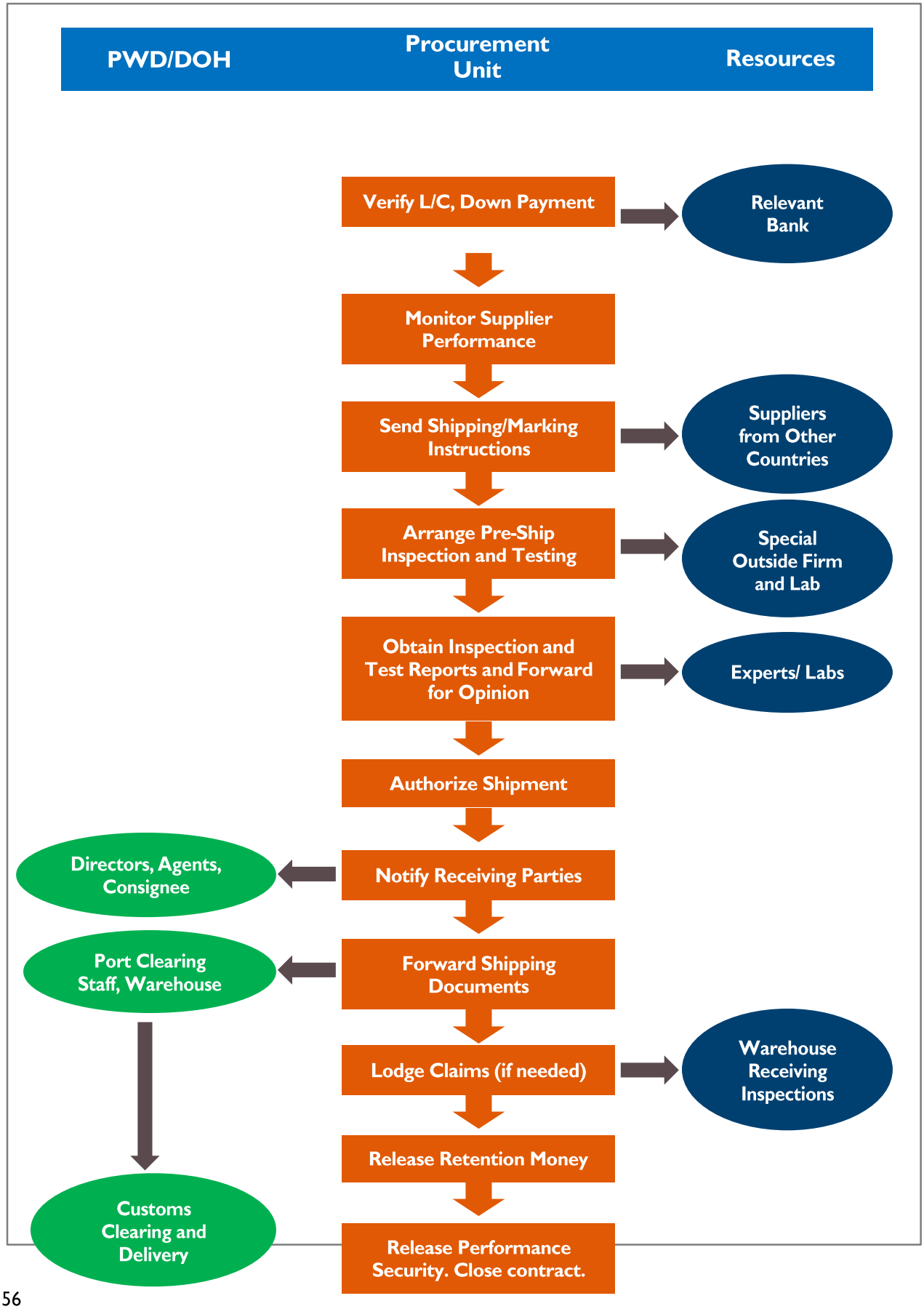
If any bidder thinks they did not receive fair and impartial treatment after submitting their bid, they can file a written complaint in accordance with *Rule 43 of PPR 2014*, after the issuance of notice inviting the tender.

The grievance committee, comprising an odd number of people, shall review the grievance and make a decision within seven days after receiving the complaint. If a bidder files a complaint, it does not automatically suspend the bidding process.

If the bidder is not satisfied with the decision of the grievance committee, they have the right to file an appeal with the review committee, in accordance with section 35 of the Act.

Module 5: Award, Contract, and Delivery




PWD/DOH
Procurement Unit
Resources
Verify L/C, Down Payment
Relevant Bank
Monitor Supplier Performance
Send Shipping/Marking Instructions
Suppliers from Other Countries
Arrange Pre-Ship Inspection and Testing
Special Outside Firm and Lab
Obtain Inspection and Test Reports and Forward for Opinion
Experts/ Labs
Authorize Shipment
Directors, Agents, Consignee
Notify Receiving Parties
Port Clearing Staff, Warehouse
Forward Shipping Documents
Lodge Claims (if needed)
Warehouse Receiving Inspections
Release Retention Money
Customs Clearing and Delivery
Release Performance Security. Close contract.

Module 5

This section includes—

A. Publication of Award
B. Notification of Acceptance
C. Performance Security and Contract
D. Payment Arrangements
E. Contract Performance Monitoring
F. Pre-Shipment Inspection and Testing
G. Shipping Clearance and Notifications
H. Shipping Documents
I. Customs Clearance and Delivery
J. Receipt of Consignment
K. Claims and Damages
L. Closing the Contract.

A. Publication of Award

The Government of Khyber Pakhtunkhwa, under *Rule 46(2) of PPR 2014*, requires the procuring entity to publish award information on their public websites within seven days of the award of contract.

B. Notification of Acceptance

Rule 50 of PPR 2014 stipulates that the bidder with the lowest evaluated cost, but not necessarily the lowest submitted price, shall be awarded the procurement contract within the original or extended period of bid validity.

Because of this rule, prior to the expiry of the bid validity period, and seven days after publishing the bid evaluation report on the KPPRA website and the website of the procuring agency (if available), the procuring entity can issue a Notification of Award (NOA) to the successful bidder. The NOA establishes a contract between the procuring entity and the successful bidder, which is confirmed later when the contract document is signed.

1. Prepare Notification Documents

The notification of acceptance must state the—

- acceptance of the bid by the procuring agency
- price at which the contract is awarded
- amount of the performance security and its format
- date and time within which the performance security must be submitted
- date and time within which the contract will be signed.

See annexure 52 for a sample NOA.

2. Resolve Minor Deviations

If the recommended bid contains minor[1] deviations that need to be resolved—

[1] For example: number of intermediate boxes in a shipping carton, equivalent documentation, differences in shipping schedules, etc.

2.1 Draft a letter that—

- states the offer is being conditionally accepted, pending resolution of outstanding issues
- lists outstanding issues and indicate the next step
- requests a response/acknowledgement

2.2 Get concurrence, as needed, before sending the letter.

2.3 If deviations are resolved, proceed to award; otherwise, select the next lowest evaluated bid approved by the relevant approving authority.[2]

3. Send the Notification of Award

The notification of acceptance cannot be sent until ten days after the bid evaluation report has been published (*Rule 50 (b) of PPR 2014*) and the award decision and the relevant authority has approved it.

3.1 Transmit the NOA to the successful bidder by registered post, courier, or hand delivery. An additional advance notice can be transmitted by email or fax.

3.2 Send copies of the NOA to the local agent of the bidder, either initially stipulated in the bid or nominated at a later stage and intimated to the purchasing office.

C. Performance Security, Contract Signing and Distribution

1. Winning Bidder Submits the Performance Security and Contract Form

1.1 The successful bidder must submit performance security, which should not exceed 10 percent of the contract value, and the signed contract form to the procuring entity within the deadline stated in the original bidding documents (*Rule 39 of SPPR, 2010–Amended 2013*). The contract form binds the bidder to the general and special conditions of the contract, and the specifications in the original bidding documents.

- Usually, the successful bidder goes to the procurement office with his agent, turns over the performance security, and signs the contract form as the first party. Alternately, the successful bidder can send the required performance security and signatures by courier.
- The person who signs the contract for the successful bidder should be the person who signed the bid; or someone who has been authorized by the person who signed the bid, in writing.

1.2 If the successful bidder fails to meet the deadline stated above, they will forfeit their bid security. The procuring agency can process for debarment of the supplier. In this case, the procuring agency should award the contract to the second lowest evaluated bidder.

2. Confirm Performance Security

As soon as the performance security is submitted, the procuring agency must have it confirmed by the issuing institution—usually a commercial bank. The same form and procedure used to confirm bid securities can be used for performance security.

[2] To save time, if the winning bidder fails to sign a contract or provide performance security, the relevant authorities usually approve the 2nd lowest evaluated bid at the same time the winning bid is approved.

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2.1 Use any legal source to confirm the performance securities issued by banks within Pakistan (local issuing banks), preferably by speaking with a bank officer at the bank.

2.2 Confirm performance securities issued by banks or other institutions outside Pakistan by email, fax, telegram, telex, letter, etc.

2.3 Use any legal source to confirm performance securities issued by banks outside Pakistan, but having a correspondent bank within Pakistan; preferably by speaking with a bank officer at the bank.

3. Sign the Contract on Behalf of Procuring Agency

3.1 After the successful bidder signs the contract form and provides performance security, arrange for the relevant authority to sign off on behalf of the procuring agency.

Note

The procuring agency cannot sign the contract until any registration for contraceptives like oral pills, injections or implants, required under the Drug Act of 1976 has been completed. It is critically important for the procurement unit to be aware of registration status and to monitor progress, because Drugs Regulatory procedures can delay contract signing and thus, the delivery date.

4. Distribute and Preserve Contract Originals

4.1 Give the supplier one of the two originals of the signed contract form.

4.2 Keep the other original signed contract form, the performance security, and the bank confirmation letter in a file using proper security and maintenance.

5. Distribute Contract Copies

5.1 Send a copy of the complete signed contact—form plus conditions and specifications, etc.—to the relevant authority and subordinate offices for recordkeeping.

5.2 For international procurement, distribute additional copies of the entire contract, as required, to the following:

- finance officer
- consignee
- central warehouse
- port clearance
- clearing and forwarding agent
- collector of customs duties and collector of sales tax at the port of entry
- supplier's local agent
- project's finance cell.

6. Notify Successful Bidder and Unsuccessful Bidders

Notify the successful bidder and the unsuccessful bidders under *Rule 45 of PPR 2014* and return bid securities to the unsuccessful bidders. Do not take this step until the successful bidder has signed the contract and provided performance security; or the bid validity period has expired and the bidder is not willing to extend the bid validity period.

7. Integrity Pact

The procuring agency shall sign an Integrity Pact with the supplier for procurements that exceed the prescribed limits (Rule 5 of PPR 2014). See Annexure 4 for a sample format of integrity pact.

D. Payment Arrangements

For local procurements, follow the payment procedure given in the bidding documents or refer to the Khyber Pakhtunkhwa procurement manual for essential medicines.

For international procurements, immediately after receiving the signed copy of the contract and confirming the performance security, the procuring agency must initiate arrangements for paying the supplier. This step should not be delayed because most international firms will not begin producing an order until they receive either a down payment or a L/C.

See Annexure 3 for detailed information about payment options.

1. Arrange Down Payment

If a down payment is required, an official of the procuring agency must request funds from the appropriate financial unit within a reasonable time. Direct bank transfer of funds is the best choice for this transaction. It should include—

- seller's name, address, bank, account number, address of bank, etc.
- reference to procurement contract number.

See annexure 2 for detailed information about letters of credit.

2. Arrange for Opening a Letter of Credit

If the contract requires a L/C, the procurement unit should—

2.1 Seek permission from the State Bank of Pakistan to apply for a L/C through a specified commercial bank: Letter of Credit Authorization (LCA).

2.2 Assemble the following information and documents:

- program name
- contract number
- name and address of the beneficiary (seller)
- name and address of the beneficiary's bank, or the L/C advising bank, as applicable
- contract amount and the currency
- short description of the contracted goods
- any other information pertinent to the L/C application form
- one copy of the contract
- one copy of the schedule of requirements.

2.3 Develop an L/C instruction sheet from the relevant sections of the contract, giving *precise instructions about the documents against which payment can be made,* shipping schedules, contract amounts, payment schedules, etc. See annexure 53 for an example. The instruction sheet helps ensure that the L/C will be issued correctly and without delay; and that all intended controls, such as conformed test findings, are in place.

2.4 Obtain L/C application forms from the designated commercial bank and prepare a draft

application.

2.5 Request the relevant finance officer to undertake opening the L/C, based on the contract document, application draft, and instruction sheet named above.

2.6 Work closely with the relevant finance officer, stay informed, and provide all possible assistance.

3. Verify Down Payment and/or Letter of Credit

The procurement office should verify that the down payment has been made and/or L/C has been issued.

3.1 Record dates of down payment and L/C issuance.

Based on these dates, the probable shipping date may need to be adjusted, because international suppliers often do not start production until the L/C (or down payment, or both) has been received. Well-constructed contracts always identify the date from which the shipping date is to be calculated.

3.2 Obtain a copy of the issued L/C, and confirm that the terms and conditions match the draft application and information provided in step 2.3.

4. Facilitate L/C Amendment, If Needed

If the L/C has mistakes, an amendment must be requested.

- Mistakes by issuing banks are possible. Usually, only a few days are allowed to make corrections without incurring amendment costs. In this case, the purchaser must notify the issuing (commercial) bank.
- Changes requested by the supplier—called the *beneficiary* in the L/C document—usually require further negotiations. In this case, the purchaser (applicant) requests an amendment from the issuing (commercial) bank, if he agrees with the supplier's (beneficiary's) request. See annexure 2 for further discussion about L/C amendments.

E. Contract Performance Monitoring

It is important for the procurement unit to stay in contact with the manufacturer (supplier) and/or his local agent during the period of manufacture and shipment.

1. Set Up and Maintain a Contract Monitoring System

1.1 List the responsibilities of the purchaser and of the supplier for contract performance. See annexure 54 for a sample list of supplier performance responsibilities.

- responsibilities tied to the normal execution of the contract, such as arrangements for inspection, provision of shipping documents, etc.
- responsibilities tied to exceptional conditions, such as notification of force majeure.

1.2 Determine a probable shipping date, based on the date of down payment or issuance of L/C and communication with the supplier.

1.3 Develop an estimated schedule for the performance of tasks and responsibilities, based on the probable shipping date and completion of the contract date. See annexure 55 for an example.

1.4 Evaluate the status of unfinished orders at least once every two weeks.

- Update the schedule with the actual dates after tasks and responsibilities are complete.
- Remind the supplier of upcoming deadlines. Ask how the work is progressing.

2. Send Shipping and Marking Instructions

2.1 Develop a separate set of shipping and marking instructions, based on the contract document; send it to the supplier at least 30 days, but not more than 60 days, before shipment. This is intended to prevent mistakes by the supplier's warehouse/shipping personnel who may not have access to the contract documents. Clear instructions help avoid delays and customs clearance problems.

2.2 See annexure 56 for an example of shipping and marking instructions.

F. Pre-Shipment Inspection and Testing

1. Compliance Program for Contraceptives and Pharmaceuticals

Contracts for contraceptives and pharmaceuticals from international sources may require special pre-shipment inspection, sampling, and testing to verify quality and compliance with specifications before shipping. This is called a *Pre-shipment Compliance Program*. To eliminate charges and countercharges of prejudice, if there is a disagreement about the outcome of the inspection and/or testing, these services may be contracted with specialized, independent third party organizations. To reduce the possibility of a supplier influencing the reports, the purchaser should not only contract for, but also pay for inspection and testing services. (See annexure 57 for a sample inspection order.)

The Pre-shipment Compliance Program, including information on sample size, is described in appendix 8.

The procurement unit, assisted by a technical expert, should arrange for any pre-shipment inspection, sampling, and testing well in advance of the expected shipping date.

1.1 Ask the technical expert to prepare a separate document for each product that states all the requirements for inspection, sampling, and testing mentioned in the contract and technical specification. This written protocol will include detailed instructions to the inspection agent and testing laboratories.

1.2 Contract with qualified inspection, sampling, and testing services that the procuring entity short-listed.

1.3 Transmit the inspection and testing protocol (step 1.1) to short-listed firms by telex/fax/email, etc., and ask for their rates. Drop any firms or agents from the short-list if they fail to respond to three consecutive requests for rates (e.g., bids) on pending inspections, if this condition was clearly stated in the IFB.

1.4 When a supplier indicates that goods are ready for shipment, notify the chosen firm and schedule the inspection (and sampling, if required) at the supplier's premises: factory, warehouse, or yard, etc.

1.5 Compare the inspection and test results to the contract requirements and obtain expert opinion on the results of compliance testing. Ask technical personnel who assisted in developing the

original specifications and provided input on bid evaluation to review the test results.

- If the specifications and test reports are the same, this step is a formality.
- If there are differences, the assigned technical expert must send its recommendation/report to the procuring agency. The procurement office makes a decision and communicates it to the supplier.

1.6 Ensure that all corrections are made.

- Re-inspection and re-testing may be required. The purchaser should control these activities, but the seller should pay for any costs associated with re-inspection and/or re-testing.
- Pharmaceutical contraceptives will be treated as per DRAP rules.

G. Shipping Clearance and Notifications

1. Authorize Shipment

When test results, expert opinion, and review by an assigned expert or committee have established confidence in the quality and acceptability of the goods proposed for shipment, it is time to authorize shipment.

1.1 Prepare a formal Authorization to Ship and forward it to the supplier, if they agree (previously) to include one in the documents required for presentation at their commercial bank for payment through the L/C. See annexure 58 for a sample authorization for shipment.

2. Provide pre-advice to port clearance staff

When a shipping date has been set, informally advise the port clearance staff, warehouse staff, and program managers.

3. Shipper's Notification to Purchaser

As soon as goods have been shipped, the contract requires the supplier to notify the purchaser and provide information on the B/L, including—

- B/L number, vessel, sailing date, and estimated time of arrival (ETA), and destination port, number of crates, weight, value, etc. (equivalent information is required for air waybills)
- copies of QA documents and certifications
- copies of commercial documents, including a pro forma invoice and packing list
- certifications for packing and marking.

4. Notify the ETA

4.1 Notify the receiving warehouse of the shipment and its ETA. This notification—

- allows time to plan warehouse space and inland transportation
- alerts warehouse and logistics staff to upcoming arrival of documents.

4.2 Notify program management of the ETA.

H. Shipping Documents

1. Seller's Distribution of Shipping Documents

1.1 For ocean shipments, the supplier turns over the goods to a freight company or freight forwarder and receives the original on-board B/L. For air shipments, they only receive a copy of the air waybill because the original is sent with the goods.

1.2 The seller puts the original B/L, or copy of the air waybill, with the other documents that the L/C requires—for example, certified QA documents or an authorization for shipment, signed by the purchaser—and presents them for payment at the commercial bank named in the L/C.

2. Consignee's Receipt and Distribution of Shipping Documents

The procuring agency, as the consignee, receives the original negotiated B/L (in other words, paid) or the air waybill copy and other shipping documents (usually, commercial invoice, packing list, and insurance papers) from the L/C opening bank.

2.1 On receipt of the shipping documents, make copies and distribute as follows:

- Customs and Forwarding agent: two sets, one is the negotiable copy
- insurance surveyor: one set for marine insurance survey
- stores: one set for store receipt and store accounting
- procurement file: multiple sets.

3. Documents to Karachi for Customs Clearance—Ocean Shipment

For ocean shipments, as soon as possible, the procurement office sends a full set of original shipping documents to the Central Warehouse in Karachi for customs clearance. Sending documents late causes delays in port clearance; demurrage charges may need to be paid after delays of as few as four days.

- Although copies of these documents may have been sent earlier, no goods can be cleared without the signed original B/L, which is a *negotiable instrument* and must be handled with secure procedures—protect it against theft, loss, forgery, etc.
- More than one original, plus several copies, of the shipping documents are usually required in the terms and conditions of the L/C. If the purchasing office needs additional certified copies, they should be requested from the L/C opening bank.

4. Documents to Local Customs Broker—Air Shipment

When air shipments arrive in Karachi, the procurement office should pass the documents on to a local customs broker, who should quickly begin clearance procedures.

- The original air waybill accompanies the goods. It does not confer ownership like an ocean B/L, so only proper identification is required to be given possession of the shipment.
- In some cases, an Exemption Certificate of Customs Duties and VAT (CDVAT) may also be required to release a delivery shipment.

I. Customs Clearance and Delivery

1. Clearance and Delivery Arrangements

As soon as the original shipping documents are received in Karachi, the *port clearing staff* must

give the required number of originals and copies to the clearing and forwarding agent who will arrange for—

- payment of port charges
- clearance from the port and customs
- joint insurance survey, both on board and at the warehouse
- insurance claims—if the consignment is insured and found damaged
- loading, offloading, and transportation from port to warehouse.

2. Pre-Release Inspection

Port clearing staff must work closely with a customs broker and attend any pre- release inspections.

3. Delivery to Receiving Warehouse

Port clearing staff will arrange for delivery to the Central Warehouse, taking all necessary steps to protect the goods.

- refrigeration of perishable products—for example, vaccine and insulin
- protection from damage due to bad weather conditions.

Sometimes, the customs broker can assist with transportation from the customs area to the receiving warehouse.

4. Warehouse Delivery Inspection

Warehouse staff must receive and inspect goods for the following details:

- correct commodity
- shipping damage
- special packing as required by the contract
- full quantities delivered
- packing slip present and correct
- correct markings on packaging, including expiry dates
- any further testing required
- manufacturer's certifications included with shipment or documents.

5. Warehouse Reports

Warehouse staff must immediately report to appropriate officials any problems found during the inspection.

J. Receipt of Consignment

1. Receiving Consignments of Imports

The *stores department* of the procuring entity will receive the shipment from the clearing and forwarding agent, including copies of the following shipping documents:

- commercial invoice
- packing list
- B/L or air waybill
- Certificate of Origin
- Certificate of Analysis

- onboard insurance survey report—if the consignment is cost, insurance and freight (CIF).

2. Receiving Consignments of Domestic Goods

If domestic delivery is on carriage paid to (CPT) basis, the documents will be copies of—

- commercial invoice
- packing list
- truck receipt
- Certificate of Analysis.

K. Claims and Damages

1. Insurance Claims

If the consignment is received with *qualified remarks*, the clearing and forwarding agent will prepare the necessary papers to lodge a marine insurance claim; including a copy of the—

- boat note
- B/L
- commercial invoice
- packing list
- survey report
- insurance policy—to be received from the supplier in CIF contracts; to be received from the purchaser in cost and freight (CFR) contracts
- claim bill.

2. Liquidated Damages

Liquidated damages are usually monetary fines imposed against the supplier for late delivery. When all shipments against the contract are complete—

2.1 Determine if the supplier has accrued any L/D. This determination process requires a review of the—

- contract terms and conditions for L/D
- B/L showing the shipment date (the date the goods were placed onboard)
- L/C advice from commercial bank showing the date it was issued
- percentage of consignment shipped within the deadlines required by the contract.

2.2 If the review reveals late shipment(s) subject to L/D, determine the amount.

3. Adjustment and Release of Retention Money

3.1 Subtract the amount of L/D determined in 2.2 from the money that has not been paid to the supplier (subtracted from the retention money). Retention money should not exceed 10 percent of the total contracted amount.

3.2 If the amount of the L/D is less than the amount of the retention money then release the remaining amount to the supplier, after deducting the L/D amount. In this case, the procurement office must—

- State in writing exactly how L/D applies.
- Determine the amount of L/D, if applicable.

- Advise the supplier of the applicability and amount of L/D.
- Mark invoices for amount to be paid after deducting the L/D amount, if applicable.
- Send invoice(s) and supporting statements and calculations to the appropriate finance office for action.

4. Warranty Claims

Check out any complaints or objections that are received from users; file warranty claims with the supplier, as needed.

L. Closing the Contract

Close the contract in accordance with PPR 2014.

1. Contract Records

At the end of the warranty period, record if—

- any warranty claim(s) have been made and if they have been settled
- any insurance claim was applicable, lodged, and processed
- any L/D were applicable and, if so, the amount of L/D deducted

2. Release of Performance Security

If no outstanding amounts are due, claims made, or other valid reservations, mark the Performance Security *released*, issue a letter to the supplier stipulating *no claim* on the Performance Security, and send a copy to the bank that issued the Performance Security.

3. Contract Files

Mark the contract file *closed* and keep it in the closed file records for a minimum of five years

Annexures

Annexure 1: Incoterms

The *international commercial terms* (*Incoterms)* are a series of pre-defined commercial terms published by the International Chamber of Commerce (ICC); they are widely used in international commercial transactions. Incoterms are a series of three-letter trade terms related to common contractual sales practices. The Incoterm rules are intended primarily to clearly communicate the tasks, costs, and risks associated with the transportation and delivery of goods. These rules are accepted by governments, legal authorities, and practitioners worldwide in interpreting the most commonly used terms in international trade. They are intended to reduce, or remove altogether, uncertainties arising from different interpretation of the rules in different countries.

Incoterms 2010

The eighth published set of pre-defined terms, *Incoterms 2010* defines 11 rules, reducing the 13 used in Incoterms 2000 by introducing two new rules (delivered at terminal (DAT); delivered at place (DAP), which replace four rules in the prior version—delivered at frontier (DAF); delivered ex ship (DES); delivered ex quay (DEQ); and delivered duty unpaid (DDU).

Note:

Carrier means any person who, in a contract of carriage, undertakes to perform or to procure the performance of, carriage by rail, road, sea, air, inland waterway or by a combination of such modes. If the buyer instructs the seller to deliver the cargo to a person—e.g., a freight forwarder who is not a *carrier*—the seller is said to have fulfilled his obligation to deliver the goods after they are in the custody of that person.

Transport terminal means a railway terminal, a freight station, a container terminal or yard, a multi-purpose cargo terminal, or any similar receiving point.

Container includes any equipment used to package cargo; e.g., all types of containers and/or flats, whether the International Standards Organization (ISO) accepted or not, swap bodies for trailers, roll-on/roll-off (Ro/Ro) equipment or igloos; it applies to all modes of transport.

Group E: Departure Term

1. Ex Works (named place of delivery)

The sellers fulfill their obligation to deliver when the goods are available for the buyer at the seller's premises: i.e., works, factory, warehouse, etc. In particular, the seller is not responsible for loading the goods on the vehicle provided by the buyer or for clearing the goods for export, unless otherwise agreed-to in the purchase contract. The buyer bears all costs and risks involved in removing the goods from the seller's premises to the desired destination. This term represents the minimum obligation for the seller.

Ex Works (EXW) should not be used when the buyer cannot carry out export formalities directly or indirectly. In such circumstances, use the free carrier (FCA) term.

Group F: Shipment Terms—Main Carriage Paid By Buyer

2. Free Carrier (FCA) (named place of delivery)

The sellers fulfill their obligation to deliver after they hand over the goods that are cleared for export to the carrier named by the buyer, at a named place or point of departure. If delivery occurs at the seller's premises, the seller is responsible for loading. If delivery occurs at any other place, the seller is not responsible for unloading. If no precise point is indicated by the buyer, the seller may choose within the place or range stipulated where the carrier shall collect the goods. When, according to commercial practice, the seller's assistance is required in making the contract with the carrier—such as in rail or air transport—the seller may act at the buyer's risk and expense.

FCA can be used for any mode of transport, including multi-modal transport.

3. Free Alongside Ship (FAS) (named port of shipment)

The seller fulfills his obligation to deliver when the goods have been placed alongside the vessel on the quay or in lighters at the named port of shipment. From that moment, the buyer has to bear all costs and risks of loss of or damage to the goods. The free alongside ship (FAS) term requires the seller to clear the goods for export and the buyer to carry out customs formalities for import.

FAS can only be used for sea or inland waterway transport.

4. Free on Board (FOB) (named port of shipment)

The seller fulfills his obligation to deliver when the goods have passed over the ship's rail at the named port of shipment. From that moment on, the buyer has to bear all costs and risks of loss of or damage to the goods. The FOB term requires the seller to clear the goods for export.

FOB can only be used for sea or inland waterway transport. When the ship's rail does not serve a practical purpose, such as Ro/Ro or container traffic, use the FCA term.

Group C: Shipment Terms—Main Carriage Paid By Seller

Under group C terms, there are two critical division points: one for the division of costs, the other for the division of risk. The seller assumes all costs, until the destination point; risks are transferred to the buyer at the point of shipment.

5. Cost and Freight (CFR) (named port of destination)

The seller must pay the costs and freight necessary to bring the goods to the named port of destination, but the risk of loss or damage to the goods, as well as any additional costs from events occurring after the goods have been delivered on board the vessel, is transferred from the seller to the buyer when the goods pass the ship's rail in the port of shipment. The CFR term requires the seller to clear the goods for export.

CFR can only be used for sea and inland waterway transport. When the ship's rail serves no practical purpose, such as in the case of Ro/Ro or container traffic, the CPT term is more appropriate.

6. Cost, Insurance, and Freight (CIF) (named port of destination)

The seller has the same obligations as under CFR but, additionally, must procure marine insurance against the buyer's risk of loss of or damage to the goods during the carriage. The seller contracts for insurance and pays the insurance premium, but the seller is only required to obtain insurance on minimum coverage. The CIF term requires the seller to clear the goods for export.

CIF can only be used for sea and inland waterway transport. When the ship's rail serves no practical purposes, such as in the case of Ro/Ro or container traffic, use the CIP term.

7. Carriage Paid To (CPT) (named place of destination)

The seller pays the freight for the carriage of the goods to the named destination. The risk of loss or damage to the goods, as well as additional costs due to events occurring after the time the goods have been delivered to the carrier, is transferred from the seller to the buyer when the goods have been delivered into the custody of the carrier. If subsequent carriers are used for the carriage to the agreed destination, the risk passes when the goods have been delivered to the first carrier. The CPT term requires the seller to clear the goods for export.

CPT can be used for any mode of transport, including multi-modal transport.

8. Carriage and Insurance Paid to (CIP) (named place of destination)

The seller has the same obligations as under CPT, but the seller also has to procure cargo insurance against the buyer's risk of loss of, or damage, to the goods during the carriage. The seller contracts for insurance and pays the insurance premium. The buyer should note that under the CIP term the seller is only required to obtain insurance on minimum coverage. The CIP term requires the seller to clear the goods for export.

This term can be used for any mode of transport, including multi-modal transport.

Group D: Arrival Terms

9. Delivered at Terminal (DAT) (named terminal at port or place of destination)

The seller pays for carriage to the terminal, except the costs related to import clearance, and the seller assumes all risks up to the point that the goods are unloaded at the terminal.

10. Delivered at Place (DAP) (named place of destination)

The seller pays for carriage to the named place, except for costs related to import clearance, and the seller assumes all risks prior to the point that the goods are ready for unloading by the buyer.

11. Delivered Duty Paid (DDP) (named place of destination)

The seller fulfills his obligation to deliver when the goods are available at the named place in the country of importation, but are not unloaded. The seller has to bear the risks and costs—including duties, taxes, and other charges of delivering the goods—until the goods are cleared for importation. If the parties want to exclude from the seller's obligations some of the costs payable upon importation of the goods—such as value-added tax (VAT)—this should be clearly stated by adding words to this effect: "Delivered duty paid, VAT unpaid (…named place of destination)."

This term can be used for any mode of transport.

Previous Terms from Incoterms 2000—Eliminated from Incoterms 2010

Delivered at Frontier (DAF) (named place)

The seller fulfills his obligation to deliver when the goods have been made available and cleared for export at the named point and place at the frontier, but before the custom's border of the adjoining country. The term *frontier* can be used for any frontier, including the country of export. Therefore, it is vitally important that the frontier in question be defined precisely by naming the point and place in the term.

This term is primarily used when goods are to be carried by rail or road, but it can be used for any mode of transport.

Delivered Ex Ship (DES) (named port of destination)

The seller fulfills his obligation to deliver when the goods have been made available to the buyer onboard the ship, but not cleared for import at the named port of destination. The seller must bear all the costs and risks involved in bringing the goods to the named port of destination.

This term can only be used for sea or inland waterway transport.

Delivered Ex Quay (DEQ) (named port of destination)

The seller fulfills the obligation to deliver when the goods are available to the buyer on the quay (wharf) at the named port of destination, but have not cleared for importation. The seller must bear all risks and costs involved in bringing the goods to the named port of destination and discharging the goods on the quay (wharf); including duties, taxes, and other charges of delivering the goods.

"Delivered duty paid, VAT unpaid (…named place of destination)."

This term can only be used for sea or inland waterway transport. It should not be used if the seller is unable, directly or indirectly, to obtain the import license.

Delivered Duty Unpaid (DDU) (named place of destination)

The seller fulfills his obligation to deliver when the goods are available at the named place in the country of importation. The seller must bear the costs and risks involved in bringing the goods—excluding duties, taxes, and other official charges payable upon importation—as well as the costs and risks of completing customs formalities. The buyer must pay any additional costs and bear any risks caused by their failure to clear the goods for import in time.

If the parties wish the seller to carry out customs formalities and bear the resulting costs and risks, this has to be made clear by adding words to this effect.

If the parties wish to include in the seller's obligations some of the costs payable upon importation of the goods (such as VAT), this should be made clear by adding words to this effect: "Delivered duty unpaid, VAT paid (…named place of destination)".

This term can be used for all modes of transport.

INCOTERMS® 2010: Responsibilities of Buyers and Sellers *(The following table explains the responsibilities of buyers & sellers including the price)*

		EXW	FCA	CPT	CIP	DAT	DAP	DDP	FAS	FOB	CFR	CIF
		Ex Works	Free Carrier	Carriage Paid To	Carriage & Insurance Paid To	Delivered at Terminal	Delivered at Place	Delivered Duty Paid	Free Alongside Ship	Free on Board	Cost & Freight	Cost Insurance & Freight
	Services / Charges	*Who Pays*	*Who Pays*	*Who Pays*	*Who Pays*	*Who Pays*	*Who Pays*	*Who Pays*	*Who Pays*	*Who Pays*	*Who Pays*	*Who Pays*
Exporting Country	Export Packing	**Seller**	**Seller**	**Seller**	**Seller**	**Seller**	**Seller**	**Seller**	**Seller**	**Seller**	**Seller**	**Seller**
	Marking & Labeling	**Seller**	**Seller**	**Seller**	**Seller**	**Seller**	**Seller**	**Seller**	**Seller**	**Seller**	**Seller**	**Seller**
	Block & Brace	1	1	1	1	1	1	1	1	1	1	1
	Export Clearance Export Duty & Taxes	**Buyer**	**Seller**	**Seller**	**Seller**	**Seller**	**Seller**	**Seller**	**Seller**	**Seller**	**Seller**	**Seller**
	Freight Forwarder Documentation Fee	**Buyer**	**Buyer**	**Seller**	**Seller**	**Seller**	**Seller**	**Seller**	**Buyer**	**Buyer**	**Seller**	**Seller**
	Inland Freight to Carrier Delivery to Port/Place	**Buyer**	2	**Seller**	**Seller**	**Seller**	**Seller**	**Seller**	**Seller**	**Seller**	**Seller**	**Seller**
	Origin Terminl Charges	**Buyer**	**Buyer**	**Seller**	**Seller**	**Seller**	**Seller**	**Seller**	**Buyer**	**Seller**	**Seller**	**Seller**
	Vessel Loading Charges	**Buyer**	**Buyer**	**Seller**	**Seller**	**Seller**	**Seller**	**Seller**	**Buyer**	**Seller**	**Seller**	**Seller**
	Ocean / Air Freight	**Buyer**	**Buyer**	**Seller**	**Seller**	**Seller**	**Seller**	**Seller**	**Buyer**	**Buyer**	**Seller**	**Seller**
	Marine Insurance	3	3	3	**Seller**	3	3	3	3	3	3	**Seller**
Importing Country	Unloading Charges	**Buyer**	**Buyer**	4	4	**Seller**	**Seller**	**Seller**	**Buyer**	**Buyer**	4	4
	Destination Terminal Charges	**Buyer**	**Buyer**	4	4	4	**Seller**	**Seller**	**Buyer**	**Buyer**	4	4
	Nominate On Carrier	**Buyer**	**Buyer**	5	5	5	5	**Seller**	**Buyer**	**Buyer**	**Buyer**	**Buyer**
	Clearing Agent Fee	**Buyer**	**Buyer**	**Buyer**	**Buyer**	**Buyer**	**Buyer**	**Seller**	**Buyer**	**Buyer**	**Buyer**	**Buyer**
	Customs, Duties, Taxes	**Buyer**	**Buyer**	**Buyer**	**Buyer**	**Buyer**	**Buyer**	**Seller**	**Buyer**	**Buyer**	**Buyer**	**Buyer**
	Delivery to Buyer Destination	**Buyer**	**Buyer**	5	5	5	5	**Seller**	**Buyer**	**Buyer**	**Buyer**	**Buyer**
	Unloading Charges at Buyer Destination	**Buyer**	**Buyer**	**Buyer**	**Buyer**	**Buyer**	**Buyer**	**Buyer**	**Buyer**	**Buyer**	**Buyer**	**Buyer**

Notes:

1	*Incoterms 2010 do not deal with the parties' obligation for stowage within a container and therefore, where relevant, the parties should deal with this in the sales contract*
2	*FCA Seller's Fcility - Buyer pays inland freight; other FCA qualifiers. Seller arranges and loads pre-crriage carrier and pays inland freight to the "F" delivery place*
3	*Incoterms 2010 does not obligate the buyer nor must the seller to insure the goods, therefore this issue be addressed elswhere in the sales contract*
4	*Charges paid by Buyer or Seller depending on contrat of carriage*
5	*Charges paid by Seller if through Bill of Lading or door-to-door rate to Buyer's destination*

3

[3] *Incoterms 2010 does not obligate the buyer or seller to pay for insurance. The purchase contract should state which party is required to pay for insurance. The charges can be paid by either the buyer or the seller, depending on the contract of carriage.*

Annexure 2: Letters of Credit

This three-page annexure presents the very basic elements for letters of credit—shown in both written and graphic form.

Opening a Letter of Credit

The buyer applies to his commercial bank to issue a L/C in favor of the seller. Exact terms are spelled out:

- how much is to be paid
- in what currency
- time limits for shipment and presentation of documents for payment
- what documents must be presented to allow the bank to pay.

In most cases, the buyer (who is now the *applicant*) will be required to deposit funds or assign already deposited funds equal to the expected payment. This is called *collateralizing* the L/C. During the time between deposit and payment, the bank can pay the buyer (applicant) interest, or provide other benefits, for the use of the funds deposited with the bank.

The commercial bank issues its document to the seller (beneficiary) with a copy to the buyer (applicant). If the document prepared by the bank is error free, a no-cost amendment can be requested. Either the buyer or the seller can request amendments to accommodate changing conditions, if both parties agree. For instance, a delivery date may need to be amended, based on an agreement between seller and the buyer.

Cost of Opening a Letter of Credit

Banks charge a percentage of the value of the goods for opening the L/C. The applicant (buyer) usually pays this charge. Banks levy additional fees for amendments, payments, and draw-downs (any change in the government taxes/levies/interest rates). The L/C should stipulate the party responsible for paying these additional fees: the beneficiary or the applicant. Fees for opening a L/C will amount to, at least, several hundred dollars. Because every bank is different, the applicant should ask for this information at the initial contact. A typical fee ranges from 0.5 percent to 1.0 percent of the face value of the L/C.

Settling a Letter of Credit

To receive payment, the beneficiary (seller) must submit specified documents to the paying bank as proof of his performance. These documents are—

- commercial invoice
- insurance certificate
- transport documents (for example, the B/L or air waybill)
- certificate of origin
- inspection certificate
- other certificates and certifications (for example, certificate of analysis).

The first three items are required. The last three items are optional and are often used by the purchaser to enforce contract provisions.

See annexure 3, Payment Options, for additional information on letters of credit.

Figure 1: Payment Process against a Letter of Credit

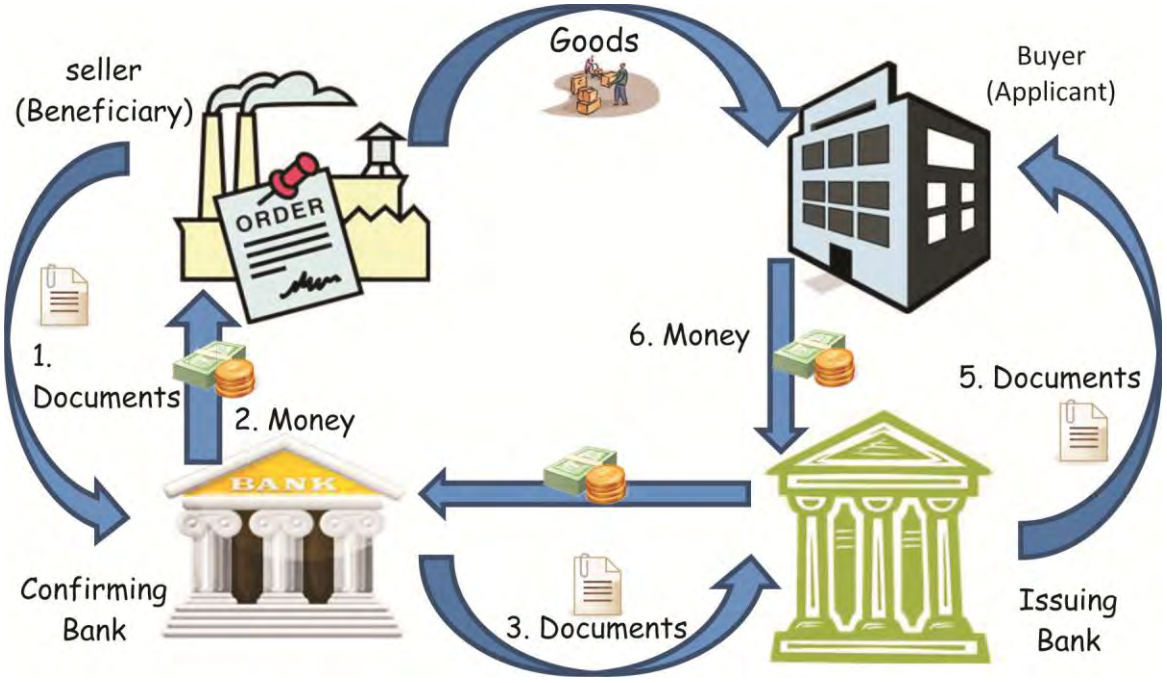
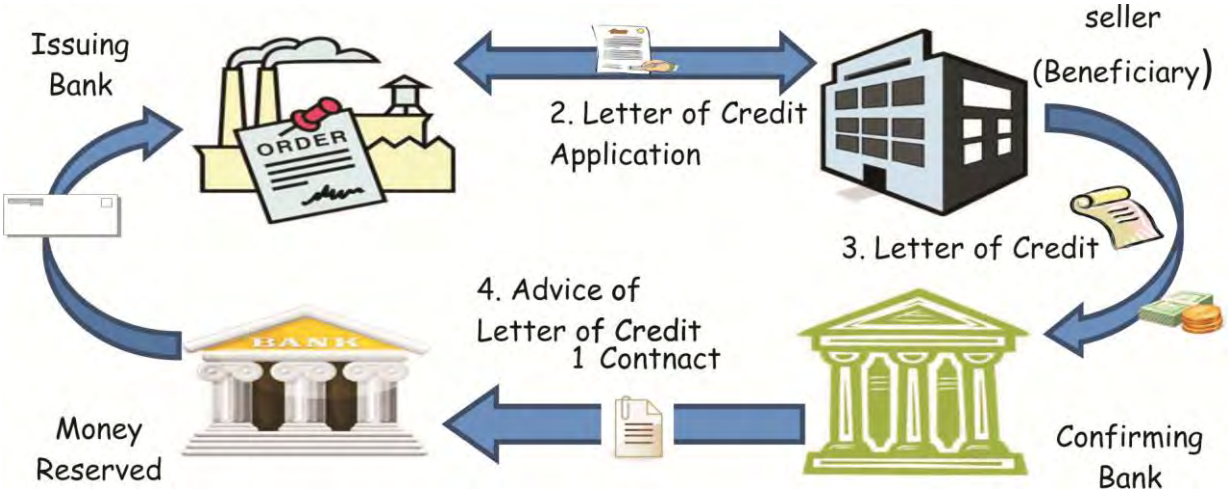


Figure 2: Opening of a Letter of Credit



Annexure 3: Payment Options

The seller usually dictates the payment terms, but the buyer can offer to negotiate. The most common payment terms are—

- cash in advance
- down payment
- on account
- payment against documents
- L/C.

1. Cash in Advance

The buyer, after purchasing the commodity under the original contract, sends the seller cash pre-payment for the entire shipment. The seller, after receiving the cash advance, ships the goods to the buyer, including all the necessary shipping documents. This is the simplest payment option.

What are the advantages and disadvantages of cash in advance?

This method of payment involves direct buyer/seller contact without involving a commercial bank; therefore, it is less expensive. However, the buyer takes on a very high degree of payment risk, while having little recourse against the seller for poor quality goods or incorrect or incomplete documentation. It's always possible that an unscrupulous seller may not deliver the goods, even though the buyer has made full prepayment.

2. Down payment

The buyer pays the seller a portion of the cost of the goods *in advance* when the contract is signed or shortly after.

What are the advantages and disadvantages of making a down payment?

The down payment method induces the seller to begin performance without the buyer paying the agreed-to price in advance. The disadvantage is the possibility the seller may never deliver the goods, even though they have the buyer's down payment. This option must be combined with one of the other options to cover the full cost of the goods.

3. Open account or *on account*

This payment method is almost the opposite of *cash in advance*. In this option, the seller essentially extends credit to the buyer. Upon shipment, the seller prepares the normal documents—such as bills of lading and original invoices—and presents these to the buyer directly, thus avoiding the involvement of a commercial bank. The buyer then pays the seller directly, usually via wire transfer, after receiving the documents.

What are the advantages and disadvantages of open account?

Under an open account payment method, the title to the goods usually passes from the seller to the buyer prior to payment; this subjects the seller to risk of default by the buyer. Furthermore, payment may be delayed, depending on how quickly documents are exchanged between seller and

buyer. While this payment term has the fewest restrictions and the lowest cost for the buyer, it also ties the seller to the highest degree of payment risk; it should only be used if the buyer and seller have a long-term relationship with a strong level of mutual trust.

4. Payment against documents

This method of payment is primarily used for ocean shipment. Generally, it should not be used for goods shipped by air because the goods would arrive well before the documents.

How does payment against documents work?

Under the original contract, the seller makes shipment and then sends the shipping documents to his bank for collection. The seller's bank sends the shipping documents, with a collection letter, to the buyer's bank which, in turn, sends a collection notice to the buyer. The buyer either makes payment upon receiving the notice and before possessing the shipping documents (a cash against documents arrangement), or the seller accepts a time draft obligating the buyer to pay at a future date (a documents against acceptance arrangement). Only after payment or acceptance does the buyer receive the original shipping documents, which confer title to the goods.

What are the advantages and disadvantages of payment against documents?

The major advantage of a *cash against documents* payment method for the buyer is the low cost, versus opening a L/C. The advantage for the seller is that he can receive full payment prior to releasing control of the documents, although this is offset by the risk that the buyer will, for some reason, reject the documents (or they will not be in order). Because the cargo would already be loaded (to generate the documents), the seller has little recourse against the buyer in case of non-payment. A payment against documents arrangement involves a high level of trust between the seller and the buyer and should be adopted only by parties well known to each other.

5. Letter of Credit

There are three major types of L/C: revocable L/C, irrevocable L/C, and confirmed irrevocable L/C. This manual discusses only the last two because a revocable L/C is rarely used.

a. Irrevocable Letter of Credit

The irrevocable commercial L/C is a banking instrument that guarantees payment to the seller (beneficiary) when they have complied with its terms. Usually, these terms include shipment of the contracted goods, compliance with specific contract requirements, and presentation of specified documentary evidence to the bank proving compliance. The bank deals in documents only, not intentions; and, therefore, allows no discrepancies without the expressed approval of the buyer (applicant).

b. Confirmed Irrevocable Letter of Credit

The seller relies on the bank's guarantee and, therefore, wants complete assurance of its reliability. When letters of credit are issued through small local banks, the confirmation of a major international bank is often required. In other cases, the seller simply wants payment to be guaranteed by a bank located in his own country. Thus, a *confirmed* L/C is a double assurance of payment: the issuing bank makes a legally binding promise to pay a beneficiary and a second bank (the confirming bank) adds its own legally binding guarantee to pay if the issuing bank defaults.

In selecting a bank to issue a L/C, it is important to choose one with an official correspondent

relationship with a major international bank so that appropriate confirmations are possible.

Separate Contracts Relating to Letters of Credit

Three separate contracts, and sometimes four, are in force under a L/C arrangement. Each contract is independent and controls its relationship with the other parties:

The sales contract between the buyer and the seller

The reimbursing agreement between the buyer (applicant) and the issuing bank (the bank that issues the L/C) is usually a deposit or set-aside of the buyer's (applicant's) funds, in their own bank, against the time the seller (beneficiary) fully complies with the requirements of the L/C and has access to the payment. The buyer (applicant) is said to have *collateralized* the L/C when he deposits or sets aside funds in the issuing bank. These funds may not be used for other purposes, but the buyer (applicant) earns interest on the deposit, or other benefits, until the L/C is paid.

The L/C between the issuing bank and the beneficiary (seller)

If the L/C is *confirmed* by another bank, that bank (the confirming bank) arranges for its own contractual arrangement with the beneficiary (seller), in addition to that of the issuing bank.

Role of advising bank

An advising bank only provides information and there is no contract. In practice, however, the advising bank may also be the confirming bank.

Advantages and Disadvantages of Letters of Credit

The L/C allows the buyer to avoid payment in advance, accrue interest (or other consideration) on deposited funds until the goods are shipped, and enforce QA provisions in the contract by linking proof of compliance to payment. This proof may be QA documents, inspection or testing certificates, or an authorization for shipment signed by the buyer's representative, based on acceptable inspection or testing results.

The confirmed, irrevocable L/C is the least risk for the seller. Because the buyer usually bears the cost of opening the L/C, it is the highest cost option for the buyer. In addition, the existence of a L/C does not obligate the seller to ship the goods purchased by the buyer.

Annexure 4:
Code of Business Ethics

Legal Reference: Government of Khyber Pakhtunkhwa Public Procurement Act 2012: Clause 16 Ethics and *Rule 5 of PPR 2014*. The Code of Business Ethics is applicable to public sector procurements.

"An employee shall not use his authority or office for personal gain. Personal gain includes accepting or requesting anything of material value from bidders, prospective bidders or suppliers for the employee, his spouse, parents, children or other close relatives, or for other persons from whom the employee might gain direct or indirect benefit from the gift."

1. Ethical Principles

Based on the legal requirement above for the Government of Khyber Pakhtunkhwa employee behavior, all employees will maintain and enhance the reputation of the provincial government; they are expected to—

- Maintain the highest standards of honesty and integrity in all relationships, both inside and outside the program where they work.
- Develop the highest possible standards of professional competence.
- Using funds and other resources for which they are responsible, provide the maximum benefit to the program and the government.
- Comply with both the letter and the spirit of the laws, rules, and regulations of the Government of Khyber Pakhtunkhwa and the Islamic Republic of Pakistan accepted professional ethics and contractual obligations.

2. Conflict of Interest

All employees shall declare any personal interest they may have in any procurement that may affect, or may reasonably be considered by others to affect, their impartiality in any matter related to their duties.

3. Confidentiality and Accuracy of Information

All employees shall respect the confidentiality of information gained in the course of their duties and shall not use any information for personal gain or for the unfair benefit of any bidder or supplier.

Information given by an employee of a national program, in the course of their duty; shall be true, fair, and not designed to mislead.

4. Competition

All employees shall treat all bidders and suppliers with fairness and impartiality, and avoid any business arrangement that might prevent the effective operation of fair competition.

5. Business Gifts

No employee shall accept business gifts from current or potential suppliers unless these gifts have

a very small intrinsic value, such as a calendar or business diary.

6. Hospitality

All employees shall refrain from accepting any business hospitality that could be viewed by others as influencing a business decision as a result of accepting that hospitality.

7. Reporting

All employees have a duty to report to their superiors, or the auditors, any unethical conduct by a colleague, bidder, or supplier.

Examples of unethical conduct include—

- Revealing confidential or *insider information,* either directly or indirectly, to any bidder or prospective bidder.
- Discussing a procurement with any bidder or prospective bidder outside the official rules and procedures for conducting procurements.
- Favoring or discriminating against any bidder or prospective bidder in the drafting of technical specifications, or standards, or the evaluation of bids.
- Destroying, damaging, hiding, removing, or improperly changing any official procurement document.
- Accepting or requesting any money, travel, meals, entertainment, gifts, favors, discounts, or anything of material value, from bidders or prospective bidders.
- Discussing or accepting future employment with a bidder or prospective bidder.
- Requesting any other employee, or government official representing the procuring agency in a procurement, to violate the public procurement rules or procedures.
- Ignoring evidence that the code of ethics has been violated by a member of a bid review committee, a civil servant, or any other employee or representative of the procuring agency.
- Ignoring illegal or unethical activity by bidders or prospective bidders, including any offer of personal inducements or rewards.

INTEGRITY PACT

DECLARATION OF FEES, COMMISSIONS AND BROKERAGE ETC.PAYABLE BY THE SUPPLIERS/CONTRACTORS OF GOODS, SERVICES &WORKS

Contract No _____ Dated: _____

Contract Value: _____

Contract Title: _____

[*the Seller/Supplier/Contractor*] hereby declares its intention not to obtain or induce the procurement of any contract, right, interest, privilege or other obligation or benefit from **Government of Khyber Pakhtunkhwa** or any administrative subdivision or agency thereof or any other entity owned or controlled by it through any corrupt business practice.

Without limiting the generality of the foregoing, [*the Seller/Supplier/Contractor*] 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 including the procurement of a contract, right, interest, privilege or other obligation or benefit in whatsoever form from Government of Khyber Pakhtunkhwa, except that which has been expressly declared pursuant hereto.

[*The Seller/Supplier/Contractor*] certifies that it has made and will 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 will not take any action to circumvent the above declaration, representation or warranty.

[*The Seller/Supplier/Contractor*] 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 Government of Khyber Pakhtunkhwa under any law, contract or other instrument, be voidable at the option of Government of Khyber Pakhtunkhwa.

Notwithstanding any rights and remedies exercised by Government of Khyber Pakhtunkhwa in this regard, [*the Seller/Supplier/Contractor*] agrees to indemnify Government of Khyber Pakhtunkhwa for any loss or damage incurred by iton account of its corrupt business practices and further pay compensation to Government of Khyber Pakhtunkhwa in an amount equivalent to ten time the sum of any commission, gratification, bribe, finder's fee or kickback given by [*the Seller/Supplier/Contractor*] 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 Government of Khyber Pakhtunkhwa.

Buyer **Seller / Supplier**

Annexure 5:
Procurement Plan Format

PROCUREMENT PLAN
Department:
Agency:
Procuring Entity Name & Code:
Project / Program Name & Code:

BUDGET:

Package No	Description of	Unit	Qty	Procurement Method and	Contract Approving	Source of	Est. Cost in Rupees	Time line	Advertise Tender	Tender Opening	Tender Evaluation	Approval To	Notification of	Signing of	Completion of	Total Time (in
1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17
Example	Oral medicines . Paracetamol Syrup, 125mg / 5ml in 60 ml bottles	Bottle	50 0,000	NCB Single stage two envelop method	DOH	Government	5 m	Planned Dates	24 May	5 July	26 July	9 Aug	16 Aug	15 Sept	13 Jan	
								Planned Days	0	42	21	14	7	30	120	234
								Actual Dates								
								Planned Dates								
								Planned Days								
								Actual Dates								
								Planned Dates								
								Planned Days								
								Actual Dates								
								Planned Dates								
								Planned Days								
								Actual Dates								
Total Value of Goods																

Annexure 6:
Financial Thresholds

Procurement Method	Source of invitation for bids	Thresholds* (As per PPR-2014 of GoKPK) in PKR	Remarks
Small Purchase	Single quotation	1/- to 49,999/-	Should be in accordance with Rule 10 of PPR 2014
Petty Purchase	Minimum three quotations	50,000/ to 100,000/	Should be in accordance with Rule 10 of PPR 2014
Direct Contracting			For all direct contracting and single source selection the rules prescribed by PPR 2014 apply
Negotiated Tendering			For all negotiated tendering the rules prescribed by PPR 2014 apply
Open Competitive Bidding (OCB)	Advertise on procuring entity's website, PPRA website, or both	over 100,000/- to 2,500,000/	It can also be advertised through print media if deemed necessary
Open Competitive Bidding (OCB)	Print media as well as websites of PPRA and procuring entity	Over 2,500,000/-	At least two national dailies; English and Urdu with nationwide circulation
International Competitive Bidding (ICB)			PPR 2014 does not provide details about financial thresholds for international procurements; however we assume the same as OCB requirements

Annexure 7: Estimated Timeline

Estimated Timeline for High Value Procurement	
3 months or more for budgeting & planning precedes initiation of procurement package	
	In days
Initiate Procurement	20
Set up file	2
Gather Pertinent Information	15
Summarize Data	3
Develop Bid Documents	25
Draft ITB, SC, Specs, Requirements	25
Solicit Receive & Open Bids	26
Place Advertisement & Notify	10
Sell Bidding Docs	15
Hold Public Bid Opening	1
Evaluate Bids Obtain Approvals	20
Complete Std Bid Evaluation	20
Notify Award	7
Receive Performance Security	
Sign Contract	7
Manufacturing Lead Time	45
Inspect at Supplier's Premises	1
Testing	10
Additional for international procurement	
Open L/C	14
Pre-shipment Quality Check	7
Authorize Shipment	2
Shipping	45

Delivery	6
Import Procedures	5
Receiving Inspection	1
Acceptance Cert.	

Annexure 8:

Procurement Requisition Form

Name of Procuring Agency

Form SPF 1
Page ____ of ____

Procurement Number					
Entity	Department / Project	Financial Year	Sequence Number	Bid Number	Contract Number
Subject of Procurement:				Location / Site:	

Item No.	Description *(A detailed Statement of Requirements of Stock Management Information may be attached)*					Quantity	Unit of Measure	Estimated Unit Cost	Estimated Total Cost

Funds Availability :	Chapter	Section	Item	Type	Estimated Total Cost:	

Signature required to certify that (1) the works, services or supplies described are required, (2) approval is granted to proceed with the procurement, and that (3) funds are available or budgeted for the requirement

	1. Originating Officer	2. Head of Department / Unit	Finance Section Officer
Signature:	_____	_____	_____
Name:	_____	_____	_____
Position:	_____	_____	_____
Date:	_____	_____	_____

Annexure 9: Procurement Requisition Form Information

This annexure contains information on preparing a procurement requisition; included is a sample procurement requisition form. This information is from the document of the former Ministries of Health and Population Welfare[4]: "*Procurement Manual Standard Operating Procedure, Procurement of Goods and Services*".

Preparing a Procurement Requisition (see requisition form SPF 1)

1. Prepare an initial description of the requirements.
2. Estimate the value of the contraceptives. The estimate can be based on recent, similar contracts; market research; or an estimate by a technical specialist. Seek assistance from technical specialists within the parent department or outside it, if required.
3. Confirm the availability of funding for the requirement. This can be ensured by the signature of an authorized finance official on the requisition form. (This official will normally be the head of the finance section in the department concerned.)
4. Obtain approval to proceed with the procurement by ensuring the signature of the budget holder, or other duly authorized official, is on the requisition form. (The budget holder will usually be the relevant program's manager duly authorized by the accounting officer).
5. Check the description of requirements, as much as possible, and attach it to the requisition form, if necessary.
6. If the requisition comes from an end user, and the procurement unit did not generate it, check the description of requirements with the end user and discuss any clarifications or changes required.
7. The officer who begins the procurement by initiating the requisition must sign the requisition form, which will certify that the contraceptives are required.

Note: Purchase requisitions should NOT mix requirements. Separate requisitions should be used for different requirements.

Approvals Required

For the following certifications, the requisition form SPF1 must be signed in three separate places, by the appropriate official:

- availability of funding for the procurement requirement in the budget, based on the estimated value on the requisition form
- confirmation of the need for the goods, works, or services listed on the requisition form
- approval to proceed with the procurement process for those items.

[4] The Manual was developed and endorsed by the federal government and was available on the Federal PPRA website. However, after the devolution of ministries to provinces and abolition of former MOH, the manual is no more available on the website.

Annexure 10: Procurement Records

Checklist for Procurement Records

Contract number:		**Bid number:**	
Supplier name:		**Bid title:**	
Date:		**Procurement contact:**	
No.	**Page No.**	**Documentation Type**	**Comments**
1		Signed procurement requisition	
2		Product specifications	
3		Budget estimate	
4		Procurement plan and summary	
5		Bidder's list	
6		Pre-qualification document	
7		Record of advertisement	
8		Bidding documents	
9		Bid security documentation	
10		Record of pre-bid conference	
11		Modifications to bidding documents	
12		Proposals from suppliers	
13		Record of bid opening	
14		Record of bid examination	
15		Bid review committee summary	
16		Award letter	
17		Performance guarantee documentation	
18		Signed contract	
19		Bidder notification	
20		Authorization for shipment	
21		Shipping documents	
22		Receiving report	
23		Miscellaneous correspondence	

Annexure 11: Table of Procurement Steps and Documents

Activity	Document
Module 1: Planning and Preparation	
Complete procurement plan	Procurement Plan
Establish procurement record	Procurement Record Checklist
Assign bid packages and tasks	
Summarize procurement	Memorandum
Module 2: Bidding Documents	
Obtain technical specifications	
Determine criteria for—	
a. Bid response	
b. Bidder qualification	
c. Contraceptive eligibility and conformity	
d. Bid evaluation	
Determine shipping terms	
Determine import procedures:	
a. Inspection/testing	
b. Documentation	
c. Licensing	
Determine payment terms	

Compile bid documents	Invitation for Bids, Instructions to Bidders, BDS, General Conditions of Contract, Special Conditions of Contract, Schedule of Requirements, Technical Specifications, Bid Form and Price Schedule, Qualification Statement
List of prospective bidders	Bidder's List
Approval of bidding documents and fact sheet	
Activity	**Document**
Module 3: Invitation for Bid	
Prepare procurement notice	
Post on GOS relevant websites, place in local and international newspapers, notify embassies, and/or direct notifications	
Prepare records and safe keeping for bid securities	
Sell bidding documents	
Hold pre-bid conference (optional)	
Record and distribute minutes to all bidders	
Answer queries and distribute clarifications to all bidders	
Module 4: Bid Opening and Selection	
Hold formal bid opening	
Record bids	Bid opening checklist
Confirm bid securities	
Bid evaluation process:	
a. Technical evaluation	
b. Qualify technically responsive bidders	
c. Financial evaluation	Templates
d. Make recommendation	

Obtain relevant authority approval	
Module 5: Award, Contract, and Delivery	
Send award notice and contract form	Award notification
Obtain and confirm performance security	
Notify unsuccessful bidders	
Release bid securities	
Arrange down payment	
Activity	**Document**
Monitor contract execution	
Pre-shipment inspection	
Shipment and notification:	
a. Authorize shipment	
b. Advise clearing agent and stores	
c. Distribute shipping documents	
Customs clearance/delivery	
Receipt of goods:	
a. Obtain documents	
b. Forward invoices to finance unit	
Claims (if applicable)	
Closing the contract:	
a. Release performance security	
b. Mark file closed	

Annexure 12: Invitation for Bids (IFB)

(insert: name of country)

(insert: name of Ministry / Department)

(insert: brief description of the Goods)

(insert: IFB title)

(insert: IFB number)

1. The (insert name of implementing agency) invites sealed bids from eligible bidders for (insert brief description of goods or works to be procured).[1]

2. Bidding will be conducted through the international competitive bidding procedures and is open to all interested eligible bidders.

3. Interested eligible bidders can obtain further information from (insert name of agency) and inspect the bidding documents at the address given below (*insert address at end of document*) from (insert office hours).[2]

4. Interested bidders can purchase a complete set of bidding documents in (insert name of language) on the submission of a written application to the address below (insert address at the end of document) and upon payment of a nonrefundable fee[3] (insert amount in local currency)or may be downloaded from the KPPRA website. The document will be sent by (insert delivery procedure).[4]

5. Bids must be delivered to the address below (insert address at the end of document) at or before (insert time and date). All bids must be accompanied by a bid security of (insert amount in local currency or minimum percentage of bid price) or an equivalent amount in a freely convertible currency.[5] Late bids will be rejected. Bids will be opened in the presence of the bidders' representatives who attend, at the address below (state address at end of document) at (insert time and date).

   (insert name of office)

   (insert name of officer)

   (insert postal address) and/or

   (insert street address)

(insert telephone number, indicate country and city code)

(insert facsimile or cable number or email address)

Footnotes to IFB

1. Provide a brief description of the type(s) of goods or works, including quantities, location of project, and other information that will enable potential bidders to decide whether or not to respond to the invitation. Bidding documents may require bidders to have specific experience or capabilities; included any restrictions in this paragraph.

2. For example, 0900 to 1200 hours.

3. The fee, to defray printing and mailing/shipping costs, should be nominal.

4. The delivery procedure is usually air mail for overseas delivery and surface mail or courier for local delivery. If urgency or security dictates, courier services may be required for overseas delivery.

5. The amount of bid security, if required, should be stated as a fixed amount, or as a minimum percentage of the bid price. Alternatively, if a bid security is not required (often the case in supply contracts), the paragraph should clearly state this.

General Note

The content of the IFB should be consistent with the BDS. The bid security shall not be less than one percent and not exceed five percent of the bid price. Also, the IFB could list key qualification criteria required for prospective bidders to be responsive, as officially specified in the BDS (e.g., minimum financial capacity, the minimum number of years during which the prospective bidder has manufactured and marketed similar goods).

Annexure 13: Evaluation and Qualification Criteria

Evaluation and qualification criteria are commonly used to help ensure that the purchaser selects a product and a manufacturer best qualified to meet the bid requirements. Standard evaluation and qualification criteria categories include—

- licensing and registration by appropriate authorities
- technical capacity and experience
- financial capability.

Examples of evaluation and qualification criteria that can be used for these categories are listed below. The purchaser can select the criteria that are most appropriate for the product to be procured. The purchaser can also include additional criteria if they are relevant and do not unduly restrict competition unfairly.

Licensing and Registration

- Product offered is registered with the required Pakistan agency (if applicable). Provide product registration number or certificate.
- Is product registered in country of origin and marketed in country of origin?
- Is product registered for export only?
- For products manufactured outside Pakistan, does the manufacture have a local authorized representative licensed in Pakistan?

Technical Capacity and Experience

- Does manufacturer have good manufacturing practices (GMP) certification? Provide a copy of the certificate.
- What is the total annual production capacity for the product the manufacturer is offering to supply?
- What percentage of the quantity of product offered in the bid is the total annual production capacity for the product?
- How many years has the manufacturer been producing the product it is offering to supply?
- What number of contracts of similar size for the product is it offering to supply have been fully successfully completed, including contact references for confirmation?

Financial Capability

- What is the total annual average international sales turnover for each of the last three years, as documented by audited financial statements.
- What is the total annual average domestic sales turnover for each of the last three years, as documented by audited financial statements.

Annexure 14: Sample Format for Fact Sheet on Bidding Document

_____ Program Fact Sheet on Bid

Contraceptives	*(insert short description)*
Quantity	
Estimated cost	*(insert cost with currency)*
Method of procurement	*(if ICB, NCB, DC, or otherwise)*
Prior review or not	*(yes or no)*
Requesting agency	*(end user)*

Annexure 15: Standard Format for Advertisement for International Competitive Bidding

(Name of Procuring Agency)

(insert title/name of bid)

Procurement number: _____

The (Name of Agency) has (allocated/received) funds (if already received, state source of funds) for the procurement of (insert title of the goods, works or services) and now invites sealed bids from eligible bidders for the supply of:

(Insert brief summary or list of the required goods)

(Insert brief narrative giving background information or further specification if necessary) Bidding is open to all suppliers/contractors who can demonstrate (list criteria for eligibility) Interested bidders may inspect the bidding document on the PPRA website www.ppra.org.pk or at the address below (insert hours between which the documents are available for inspection). Bidding documents may be purchased upon payment of a nonrefundable fee of (insert fee amount, currency and payment format).

Bids must be delivered to the address below on or before (insert date and time of bid closing). All bids must be accompanied by:

- A bid security of not less than (insert fixed figure or percentage of the bid price);
- List all other required documents and samples where applicable.

Bids will be opened on (date) at (time), in the presence of bidders' representatives who choose to attend, at the address below. (If at a different address, state the address). Late bids will be rejected and returned unopened to bidders.

(Insert full name of procuring agency):	City or Town, Postcode and Province:
Room Number:	Name and/or title of person to contact:
Building Name:	Telephone Number:
Street number and name (if appropriate):	Fax Number:
Sector:	Email address (if available):

There will be no price negotiations with the lowest evaluated responsive bidders. Suppliers are, therefore, requested to submit their lowest and best prices with their bids.

Annexure 16: Sample Format for the Minutes of Pre-Bid Conference

Minutes of the Pre-Bid Conference on Bid Package No. (*insert number*)

1. Meeting date, place, and time:
2. Bid package no.:
3. Bidders represented: (*insert names of bidders*)
4. Discussion of the conference:

Query and Reference	**Reply/Clarification**
(insert page no., paragraph no., section no. etc.)	*(insert the exact reply/clarification)*

Annexure 17: Sample Format for Forwarding Queries Raised in Pre-Bid Conference

Memo No._____ Date _____

Government of Khyber Pakhtunkhwa

Population Welfare Department

(Mention address)

To

Technical expert

Subject: Request for Clarification on query raised in pre-bid conference on

Bid package No. --- for (*mention name of goods)*

Ref: Pre-bid conference held on (*mention date*)

Dear Sir:

Queries raised in the pre-bid conference held on the subject bid package on (*mention date*) are mentioned in the attached copy of the minutes of the above-mentioned pre-bid conference for your clarification and necessary action.

We will appreciate your earliest response to the above. Please note that the bids are due for submission on (*mention bid submission date*).

Thanking you,

Copy for information to:

1. The user office.

Annexure 18: Sample Format for Replying to Queries Raised in Pre-Bid Conference

Memo No._____ Date_____

Government of Khyber Pakhtunkhwa

Population Welfare Department

(Mention address)

To

All Bidders

(*mention the names and addresses*)

Subject: Clarification on query raised in Pre-bid conference on

Bid Package No. --- for (*mention name of goods*)

Ref: Pre-bid Conference held on (*mention date*)

Dear Sir:

Clarifications/replies to queries raised in the pre-bid conference on the subject bid package on (*mention date*) are mentioned for your information and necessary action.

Query and Reference	Reply/Clarification
(*mention page no., paragraph no., section no, etc.)*	(*mention the exact reply/clarification*)

Thanking you,

Copy for information to:

1. GOKPK
2. The User office

Annexure 19: Sample Format for Notification on Extension of Bid Submission Date

Memo No._____ Date_____

Government of Khyber Pakhtunkhwa

Population Welfare Department

(Mention address)

To

M/S

(*All bidders who have purchased the Bid Package*)

Subject: Notification on extension of Bid submission date for Bid package No. ---- for (*mention name of goods*)

In order to facilitate necessary actions on the reply/clarification to queries raised in the pre-bid conference held on the subject bid package on (*mention date*) the Bidding Document selling date and bid submission date are hereby extended as follows:

Event	Previous Date	Extended Date
Bidding Document	Up to (*mention date*)	Up to (*mention date*)
Bid submission date	(*mention date)*	(*mention date)*

We will appreciate your earliest response to the above. Please note that the bids aredue for submission on (*mention bid submission date*).

Thanking you,

Copy for information to: 1. NNRA

2. The User office.

Annexure 20: Standard Bid Evaluation Forms

Section I. Bid Evaluation Standard Forms

Standard Cover Letter of Transmittal

Table 1. Identification

Table 2. Bidding Process

Table 3. Bid Submission and Opening

Table 4. Preliminary Examination & Technical Evaluation

Table 5. Bid Prices (as read out)

Table 6. Corrections and Unconditional Discounts

Table 7. Exchange Rates

Table 8. Currency Conversion (multiple currencies)

Table 9. Currency Conversion (single currency)

Table 10. Additions, Adjustments and Priced Deviations

Table 11. Domestic Preference for Goods

Table 12. Domestic Preference for Works

Table 13. Proposed Contract Award

Annexure 21: Sample Format for Notification of Bid Opening

Memo No._____ Date_____

Government of Khyber Pakhtunkhwa

Population Welfare Department

(Mention address)

NOTIFICATION

Bids against Bid Package No. ---- will be opened on (mention date, time, and venue.) Salient information about the package is given below.

Bid Package Number	Goods	Quantity	Estimated Cost	Method of Procurement
	(Mention short Description)	(Mention Quantity with unit)	(Mention cost with currency)	(Mention whether ICB, NCB, DC or otherwise)

All members of the Bid Opening Committee are requested to kindly attend the meeting.

CC:

Copy for information and necessary action:

all members of Bid Opening Committee.

Annexure 22: Record of Samples Received from Suppliers

Name of Procuring Agency _____ Form SPF 8

Record of Samples Received from Suppliers

Procurement Number					
Entity	Department/ Project	Financial Year	Sequence Number	Bid Number	Contract Number

Subject of Procurement:	

S. N	Item	Supplier	Date Received	Test S. N.	Date Sent for Test	Date Returned	Remarks

Annexure 23:
Bid Opening Checklist

Bid Opening Checklist

(To be filled out for each bid as it is read out)

Contract reference: _____

Bid opening date: _____ Time: _____

Name of bidder: _____

1. Is outer envelope of bid sealed?
2. Is the bid form completed and signed?
3. Expiration date of bid:
4. Is documentary authority for signing enclosed?
5. Describe any substitution, withdrawal, or modification submitted.
6. Describe any alternative bid made:
7. Describe any discounts or modifications offered:
8. Name of bidder or representative present:
9. Is inner financial bid envelop sealed?

Signature of responsible official: _____

Date: _____

Annexure 24:
Record of Bid Opening

Record of Bid Opening

Name of project/contract: _____

Invitation for bid no.: _____

Date: _____

Time: _____

	Bidder's Name and Address	Local Agent's Name and Address	Bid Currency	Modifications or Comments (discounts, withdrawals, missing bid security, etc.)
1.				
2.				
3.				
4.				

Bidders Present

	Name	Company	Signature
1.			
2.			
Etc.			

Members of Bid/Tender Opening Committee

	Name	Signature
1.		
2.		
Etc.		

Annexure 25: Guidance Notes on Bid Opening

(Extracted from *Manual of Procurement Policies and Standard Operating Procedures for the NHF Programs of the former Ministries of Health and Population Welfare, Government of Pakistan SOP 19)*

Guidance Notes on Bid Opening

1. Prepare the room prior to the bid opening time. Staff must ensure that appropriate resources, both physical and human, are available to efficiently manage the bid opening.
2. The person chairing the opening must ensure that all staff involved understand their respective roles in the procedure.
3. The chairperson of the bid opening committee welcomes bidders to the opening and asks them to sign the record of attendance. He/she briefly explains the usual procedure that will be followed: open the sealed bid box, count the bids, open the bids, PA reads and records the information, give the bidders the opportunity to ask questions, close the meeting, and remove the bids for safekeeping and evaluation.
4. Show the seal of the bid box to everyone present at the bid opening committee meeting; break the seal.
5. Open the bid box; remove and count all the bids.
6. First, open the envelopes marked *Withdrawal,* one at a time. Read these out loud, locate the envelope containing the corresponding bid, and return to the bidder unopened. Note the withdrawal on the record of the bid opening.

N.B. Withdrawals are bidders who, after submitting a bid well in advance, withdraw their bids and do not want their bids to be considered.

7. Next, open envelopes marked *Modification* one at a time; locate and open the envelope containing the corresponding bid. Read out and record the details of the modified bid; ensure that the details relate to the modified, not the original, bid. Stamp both the original bid and modification on key pages; the chairperson of the opening signs or initials; and, if required, all members of the bid opening committee sign or initial.

N.B. Modifications refer to bidders who, after submitting a bid well in advance, have modified the terms of their bid (e.g., result of an unexpected change in the price of a key manufacturing input) and have placed another envelope marked *Modification* in the bid box before the date and time of the bid opening.

8. Count the remaining bids, then mark each bid envelope with a serial number; begin with the number 1.
9. List the bids in numerical order. Open the bids one at a time; read the relevant details; use the Record of Bid Opening form and record each bid as a line item against each serial number.

10. Stamp each bid on key pages; the chairperson of the opening signs or initials; all members of the bid opening committee counter-sign the pages. Mark each bid with a number (1, 2, 3, etc.), that corresponds to its number on the bid opening record. With the exception of late bids, the bid opening committee cannot comment on the acceptance or rejection of any bid. Note any missing or incorrect documents in the record of bid opening, but without comments.

11. After all the bids received on time have been opened, read out, and recorded.

State in the bidding document the information to be read out loud. This must include, at least—

- the name and address of each bidder
- the total price of each bid, stating the currency and amount
- each unit price quoted (in addition to the total price or lot prices to be read out) stating the currency and amount.

It may also include—

- the presence or absence of a bid security, and the form and amount of the bid security, if one was requested in the bidding document
- any other details stated in the bidding document.

Do not read out additional information concerning any bid, except that required by the bidding document.

12. The chairperson of the bid opening committee closes the bid opening meeting, reminding bidders that they must not try to influence the evaluation and the bid evaluation report will be announced in due course, in accordance with *Rule 29 of PPR 2014*.

13. Distribute copies of the bid opening record to bidders, on request. Add the original record to the procurement file.

14. Immediately place all bids in a place for safe keeping, until the evaluation committee is ready to meet. Keep all bid securities in a secure location.

Annexure 26: Sample Format for Confirmation of Bid Security

Memo No._____ Date_____

Government of Khyber Pakhtunkhwa

Population Welfare Department

(Mention address)

Manager, Issuing Bank

(*Mention name and address of the bank branch as evident from the Bid Security*)

Subject: Bank Guarantee/Pay Order/Cashier's Cheque (*mention no. & date*)

You are requested to kindly confirm issuance of the above-mentioned Bank Guarantee/Pay Order/Cashier's Cheque (*mention no. & date*) submitted to us by (*mention the bidder's name and address*) against bid package no. (*mention no.*).

Salient information about the instrument is given below.

Type of Guarantee	Issued in favor of	Amount and currency	Validity
(mention whether it is a Bank Guarantee or Pay Order or Otherwise)	*(mention bidder's name)*	*(mention amount and currency)*	*(mention period)*

Your early response will be highly appreciated.

Annexure 27: Table 1. Identification

1.1 Program name:	
1.2 Funding source:	
1.3 Date of effectiveness:	
1.4 Closing date: (a) original: (b) revised:	
1.5 Name of project:	
1.6 Purchaser: (a) name: (b) address:	
1.7 Contract number (identification):	
1.8 Contract description:	
1.9 Cost estimate[1]:	
1.10 Method of procurement: (check one)	ICB _____ NCB _____ Other _____
1.11 Prior review required[2]	Yes _____ No _____
1.12 Domestic preference allowed:	Yes _____ No _____
1.13 Fixed price contract:	Yes _____ No _____

[1] Budget allocation, including foreign exchange component

[2] If response is *no*, items 2.2(b), 2.4(b), and 2.6(b) in table 2 can be left blank.

Annexure 28: Table 2. Bidding Process

2.1 Specific procurement notice	
(a) Name of national newspaper:	
(b) Issue date:	
(c) Name of international publication:	
(d) Issue date:	
(e) PPRA website date:	
2.2 Standard bidding document	
(a) Title, publication date:	
(b) Date of issue to bidders:	
2.3 Number of firms issued documents:	
2.4 Amendments to documents, if any:	
(a) List all issue dates:	1.____2. ____3._____. 1._____2. ____3._____.
2.5 Date of pre-bid conference, if any:	
2.6 Date minutes of conference sent to bidders:	

Annexure 29: Table 3. Bid Submission and Opening

3.1 Bid submission deadline	
(a) Original date, time:	
(b) Extensions, if any:	
3.2 Bid opening date, time:	
3.3 Record of bid opening:	
3.4 Number of bids submitted:	
3.5 Bid validity period (days or weeks):	
(a) Originally specified:	
(b) Extensions, if any:	

Annexure 30: Table 4. Preliminary Examination & Technical Evaluation

Bidder *(a)*	Verification *(b)*	Eligibility *(c)*	Completeness of Bid *(d)*	Substantial Responsiveness *(e)*	Acceptance for Detailed Examination *(f)*	

Annexure 31: Table 5. Bid Prices (as read out)

Bidder Identification			Read-out Bid Price(s)[1]		Modifications or Comments[2] *(f)*
Name *(a)*	City/Province *(b)*	Country ©	Currency(ies) *(d)*	Amount(s) or % *(e)*	

[1] For single currency option (see Annex 1, Para. 6(d)(ii)), secondary currencies are expressed in column e as a percentage of the total bid price

[2] Describe any modifications to the read-out bid, such as discounts offered, withdrawals and alternative bids. Note also the absence of any required bid security or other critical items

Annexure 32: Technical Evaluation Sub-Schedule for Table 4

Technical Evaluation Sub-Schedule for Table 4 (column e)

Name of Bidder:_____ Contract No.:_____

Name of Item: _____

	Specification per Bidding Document	Remarks (acceptable, unacceptable—if unacceptable, provide reasons)
1		
2		
3		
4		
5		

Offered product's brand name: _____

Overall comments:

(If product mentioned above is other than what was specified in the bidding documents, please state whether or not the substituted product offers substantial equivalence in critical performance parameters or in other requirements.)

Signature of technical expert:_____
Date:_____

Annexure 33: Summary of Technical Evaluation

Name of Procuring Agency: Form SPF 4

Page __of ___

Procurement Number					
Agency	**Department/ Project**	**Financial Year**	**Sequence Number**	**Bid Number**	**Contract Number**

No.	**Bidder**	**Technical Compliance**	**Comments (reason for non-compliance)**
1		C/NC	
2		C/NC	
3		C/NC	
4		C/NC	
5		C/NC	
6		C/NC	

Key: **C** Denotes compliant **NC** Denotes non-compliant

This examination eliminated (*insert number*) companies, (*insert names of companies*).

List names of companies eliminated on separate sheet(s).

Attach combined technical specification and compliance sheets for each quotation/ tender if technical evaluation is complex.

Annexure 34: Verification Checklist for SBEF Table 4 (column b)

Verification Checklist for SBEF Table 4 (column b)

Bidder's Name_____ Contract Number_____

1. Bid validity period conforms to the requirement in the bidding documents? (yes /no)

2. If the bidder is a joint venture, Joint Venture agreement provided? (yes /no /not applicable)

3. If the bidder is not the manufacturer, whether bidder provided Manufacturer's confirmation to warranty obligations? (yes /no /not applicable)

4. If the bid has been submitted by an agent, whether the Manufacturer's Authorization to submit the bid is provided? (yes /no /not applicable)

Annexure 35: Eligibility Checklist for SBEF Table 4 (column c)

Eligibility Checklist for SBEF Table 4 (column c)

Bidder's Name_____ Contract No._____

1. Has this bidder been pre-qualified? (yes/no/not applicable)

2. Is bidder a national of an eligible source country? (yes/no)

3. If bid is from a joint venture, are all partners nationals of an eligible source country? (yes/no/not applicable)

4. If bid is from a joint venture, is the joint venture registered in an eligible source country? (yes/no/not applicable)

5. Do the goods and/or services offered originate from eligible source countries? (yes/no)

6. If the bidder is a publicly owned enterprise in Pakistan, is the bidder legally and financially autonomous and operating under commercial law? (yes/no/not applicable)

Annexure 36:
Bid Security Checklist

Bid Security Checklist

Name of Bidder_____ Contract No._____

1. Is bid accompanied by bid security? (yes/no)

2. Does the amount of the bid security conform to the amount required in the bidding documents? (yes/no)

3. Does the period of the bid security conform to the period required in the bidding documents? (yes/no)

4. If bid security is issued as a bank guarantee, is it consistent with the wording of the bid security form provided in the bidding document? (yes/no/ not applicable)

5. If the bid is submitted by a joint venture, is the bid security in the name of all of partners of the joint venture? (yes/no/not applicable)

Annexure 37: Completeness of Bid Checklist for SBEF Table 4 (column d)

Completeness of Bid Checklist for SBEF Table 4 (column d)

Bidder's Name_____ Contract No._____

1. Does the Bidder offer all of the required items? (yes/no)

2. Does the Bidder offer full quantities of the required items? (yes/no)

3. Has the Bidder made any additions, deletions or other changes to the original bidding documents? (yes/no)

4. Has the Bidder initialed any erasures, additions, deletions or other changes to the original bidding documents? (yes/no)

5. Are all pages of the bidding document and the bid included in the submission? (yes/no)

6. Are all of the required documents and attachments included with the bid? (yes/no) (If no, list missing items.)

Annexure 38: Commercial Responsiveness Sub-Schedule for SBEF Table 4 (column e)

Commercial Responsiveness Sub-Schedule for SBEF Table 4 (column e)

Bidder's Name_____ Contract No._____

1. Does the Bidder ask for price adjustments when a fixed price bid was invited? (yes/no)

2. Does the Bidder offer an alternative design in the bid? (yes/no)

3. What is the completion/delivery time offered in the bid?

4. Does the completion/delivery time offered in the bid conform to the Schedule of Requirements in the Bidding Documents? (yes/no)

5. Is any sub-contracting mentioned in the bid? (yes/no)

6. Does the bidder agree to bear the responsibilities and liabilities allocated in the bidding documents, such as performance securities, insurance coverage, etc? (yes/no) If no, provide details.

7. Does the bidder agree to applicable law, taxes and duties and dispute resolution procedures specifies in the bidding documents? (yes/no) If no, provide details.

Annexure 39: Table 6. Corrections and Unconditional Discounts

Bidder	Read-out Bid Price(s)		Corrections		Corrected Bid Price(s)	Unconditional Discounts[2]		Corrected/ Discounted Bid Price(s)
	Currency(ies)	Amount(s)	Computational Errors[1]	Provisional Sums		Percentage	Amount(s)	
(a)	*(b)*	*(c)*	*(d)*	*(e)*	*(f)= © + (d) – (e)*	*(g)*	*(h)*	*(i)=(f)-(h)*

Note: Only bids accepted for preliminary examination (Table 5, column *g*) should be included in this and subsequent tables. Columns *a, b*, and *c* are from Table 4 (columns *a, d*, and *e*, respectively).

[1] Corrections in column *d* can be positive or negative.

[2] If the discount is a percentage, column *h* is usually the product of the amounts in columns *f* and *g*. If the discount is an amount, it is entered directly in column *h*. A price increase is a negative discount.

Annexure 40: Table 7. Exchange Rates

Currency used for bid evaluation: _____

Effective date of exchange rate: _____

Authority or publication specified for exchange rate: _____

Note: *Attach copy of exchange rates provided by specified authority or publication.*

Annexure 41: Table 8. Currency Conversion (multiple currencies)

Specify evaluation currency: _____

Bidder	Currency(ies) of Bid	Corrected Discounted Bid Price(s)	Applicable	Evaluation Currency	
(a)	*(b)*	*(c)*	Exchange Rate(s)[1] *(d)*	*Bid Price(s) (e)=(c)x(d)*	Total Bid Price[2] *(f)*

Note: This table is to be used for SBDLW. Columns *a, b* and *c* are from Table 6, columns *a*, *b*, and *i*
[1] Column *d* is from Table 7.
[2] Column *f* is the sum of bid prices in column *e* for each bidder

Table 9: Currency Conversion (single currency)

Bidder *(a)*	Currency of Bid *(b)*	Corrected Discounted Bid Price *(c)*	Applicable	Evaluation Currency	
			Exchange Rate[1] *(d)*	***Bid Price(s)*** *(e)=(c)x(d)*	**Total Bid Price[2]** *(f)*

Note: This table is to be used for SBDLW. Columns *a, b* and *c* are from Table 6, columns *a*, *b*, and *i*

[1] Column *d* is from Table 7.

[2] Column *f* is the sum of bid prices in column *e* for each bidder

Annexure 42: Table 10. Additions, Adjustments and Priced Deviations

Specify evaluation currency:

Bidder *(a)*	Corrected Discounted Bid Price [1] *(b)*	Additions[2] *(c)*	Adjustments[2] *(d)*	Priced Deviations[2] *(e)*	Total Price *(f) = (b)+(c)+(d)+(e)*

Note: See paragraph G.4.1 in Module 4 for an explanation of the term *Additions*.
[1] Column *b* is from Table 8 column *f*.
[2] Add a footnote for each insertion in columns *c, d,* or e and explain in adequate detail, including calculations.

Annexure 43: Table 11. Domestic Preference for Goods

Specify evaluation currency: _____

Bidder	Domestic Preference Group[1]	Total Price[2]	Exclusions For Preference[3]	Revised Total	Prevailing Tariff (%)[4]	Domestic Preference (%)[5]	Preference Price[6]	Total Comparison Price
(a)	*(b)*	*(c)*	*(d)*	*(e)=(c)-(d)*	*(f)*	*(g)*	*(h)*	*(i)=(c)+(h)*

[1] Column *b* refers to group A, B, C, as indicated by bidder, subject to verification by the borrower.

[2] Column *c* is from Table 10, Column *f*. If the lowest total price is from a Group A or Group B bidder, and it is the lowest evaluated bidder, the remainder of the table does not need to be filled out. Fill out columns *d* through *h* for Group C bids only.

[3] Column *d* is the sum of costs in columns *d* and *e* from Table 10, plus other costs incurred within the borrower's country. Insert footnote to explain the significant components of column *d*.

[4] Column *f* is the sum of duties and import taxes on the particular items, or group of similar items, as a percentage of the CIF or CIP price.

[5] Column *g* will have the lowest of 15 percent or the prevailing tariff in column *f*.

[6] Column *h* for Group A bidders is zero. At this stage, do not compare Group B bids. For Group C bidders, column *h* is the product of columns *e* and *g*.

Annexure 44:
Ranking Worksheet

Ranking Worksheet

Bid no.: _____

Bid opening date: _____

Bidder	Total Bid Price	Ranking*

**Prior to any cross discounts that may be applicable*

Annexure 45:
Cross Discount Worksheet

Cross Discount Worksheet					
Bidder	**Bid Packages Grouped by Bidder for Discount**	**% Discount Offered**	**Discounted Price of Bid Packages (b) x (c)**	**Prices Offered by the Lowest Evaluated Bidders for Column (b) Packages**	**Comparison Column d Total and Column c Totals**
(a)	(b)	(c)	(d)	(e)	(f)
	1.				
	2.				
	3.				
			(total)	1.	
				2.	
				3.	
				(total)	

Cross Discounts

The bidder offers the purchaser these conditional discounts when more than one contract or lot could be awarded to the same bidder. The bid evaluation committee must select the best combination of awards, based on the least overall cost of the total contract package. Bid evaluation in these cases can be complicated, with many possible variations.

The cross discount worksheet shows an example of basic information and calculations needed to determine whether it would be less expensive to purchase a group of bid packages individually from each of the lowest evaluated bidders, or as a group of bid packages from one bidder who offers a discount applied to the total.

Instructions for completing cross discount worksheet:

Column a (first line): Enter the name of the bidder offering a conditional discount.

Column b (first line): List the bid packages in *column a* that the bidder would discount if all packages in the group were awarded to that bidder. Include the package number and the price without the discount.

Column c (first line): Enter the discount offered by the bidder (usually a percentage).

Column d: Apply the discount in *column c* to each bid package price noted in *column b* to determine a discounted price for each bid package; next, calculate the sum of the discounted bid package prices; enter that amount on the first line of *column d*.

Column e: Starting on the second line, list the lowest evaluated bidder for each separate bid package in *column a*, the corresponding bid package number in *column b*, and the bid prices in *column e*; next, calculate the sum of the lowest evaluated bid prices and enter the total on the first line of *column e*.

Column f: Indicate the lower price from *column d* and *e*; include remarks.

Annexure 46: Sample Worksheet Bidder's Qualification Criteria

A. Manufacturer has adequate production capability

1. Annual capacity for production of subject goods is at least three times the quantity specified in the schedule of requirements for this bid.
2. Installed manufacturing capacity for subject goods minus the existing contracts for the delivery of subject goods exceeds quantities specified in schedule of requirements for the same period.

B. Bidder has verifiable business and financial stability

1. Manufacturer's average annual sales value during the past three years is at least five times the estimated contract value (requires calculation).
2. Manufacturer has produced the specific goods that are the subject of bidding for at least two years, and for similar goods for at least five years.
3. Agent, if applicable, has marketed specific or similar goods for at least three years.
4. Manufacturer is licensed, or otherwise registered, with tax authorities for doing business in the country of domicile.
5. Agent, if applicable, is licensed, or otherwise registered, with tax authorities for doing business in Pakistan.
6. Manufacturer has maintained a business bank account for at least five years.
7. Agent, if applicable, has maintained a business bank account for at least three years.

C. Manufacturer has verifiable technical capability

1. Manufacturer of goods has a valid license issued by the competent regulatory authority in the country of manufacture.
2. Manufacturer of goods has received satisfactory GMP inspection in line with the World Health Organization certification scheme on pharmaceuticals moving in international commerce from regulatory authority in the country of manufacture, within the two years prior to bid.
   ….or….
3. Manufacturer has been certified by the competent authority of a member country of the Pharmaceuticals Inspection Convention and has demonstrated compliance with the quality standards during the two years prior to bid.
4. Manufacturer has on-site QC, QA testing facilities.

D. Bidder has verifiable history of successful performance

1. The bidder has not less than three and not more than five (usually four) similar contracts completed not less than within the last five years, depending on the size and complexity of the subject contract.
2. Reference check reveals satisfactory business dealings with at least five similar customers.
3. Reference check with at least five similar customers reveals satisfactory quality of products supplied.

Annexure 47:
Bid Evaluation Report

(Extracted from *Manual of Procurement Policies and Standard Operating Procedures for the NHF Programs of the former Ministries of Health and Population Welfare, Government of Pakistan*.)

Name of Procuring Agency: Form SPF 4

Page __of ___

Bid Evaluation Report

Procurement Number					
PA	**Department /Project**	**Financial Year**	**Sequence Number**	**Bid Number**	**Contract Number**

Introduction

The requirement is for the procurement of (*insert subject of procurement*).

The procurement method used and approved by the relevant authority (RA) was (*Open Tender Limited Tender/Request for Quotations/Direct Procurement*).

Details of Invitation

The bidding documents were approved by the (RA) on (*insert date*). The announcement was advertised on the (*insert date*) in (*insert name of publications*). A list of bidders purchasing the bidding documents is attached.

(or for limited tender/request for quote (RFQ) or following prequalification for this tender)

The RA approved the bidding documents on (*insert date*). The shortlist of bidders was selected by the following method (*explain method of selection*).

Other Bidding Information

(List any other information on the bidding process, including any pre-bid meeting, clarifications requested, or extensions of bidding period; list and attach the appropriate records.)

Bid Closing

Bids were closed on (*insert date*) at (*insert time*) at (*insert location*).

Details of Bid Opening/Quotation Opening

Bids were opened in public at *(insert location*) by the bid opening committee on (*insert date*) at (*insert time*). Copies of the record of bid opening, the register of attendance, and the record of samples received are attached.

(*Explain any important issues that arose during the bid opening procedures.*)

The sealed quotations were opened at (*insert location*) by the bid opening committee on (*insert date*) at (*insert time*). Copies of the record of bid opening, the register of attendance, and the record of samples received are attached.

Evaluation Procedures

The technical (evaluation) committee included the following officials:

(Name) (Position) (Chairman of evaluation committee)

(Name) (Position)

(Name) (Position)

(Name) (Position)

Evaluation Methodology

The evaluation method specified in the bidding documents was the lowest priced bid (least cost selection) of the technically compliant and responsive bids.

(Explain important evaluation criteria, such as evaluated price adjustments [e.g., for delays] to be used in determining the best evaluated bid; acceptable deviations from the confidential price estimate; or other criteria, as specified in the bidding documents.)

Preliminary Examination of Bids

Bids were examined to determine the—

- submission of the required bid security
- commercial responsiveness of each bid to the Invitation
- eligibility and qualifications of the bidder.

The results of this preliminary examination are given in table 1, which is attached.

(Explain why any bids were declared non-responsive and rejected during the preliminary examination.)

Technical Evaluation

4. Technical evaluation determined the compliance of each responsive bid to the technical specification issued in the bidding documents.
5. {Samples submitted were inspected and confirmed to be acceptable. Technical evaluation was

conducted only on a pass/fail basis. Only bids that passed both the preliminary responsiveness and technical compliance tests were considered for financial evaluation.

The evaluation of the technical specifications of all bids is summarized in table 2.

(Briefly describe the results of the technical evaluation, including detailed justification as to why any bids were declared non-compliant.)

Financial Evaluation (of technically compliant and responsive bids)

All responsive and technically compliant bids were examined and tabulated in table 3 to—

6. record the submitted bid prices
7. correct for any omissions or arithmetic mistakes
8. convert the bid prices to Pakistani rupees, if necessary
9. adjust the bid prices for criteria specified in the bidding document, such as delayed delivery penalties, to arrive at the evaluated bid price for comparison
10. rank bids based on the lowest evaluated price.

(For each bid, describe any corrections, errors in calculations, penalties added to the bid price for evaluation purposes, and conversion to a common currency, if necessary.)

Qualification (if no pre-qualification procedure was used)

The qualification, as per *Rule 17*, is subject to reasons to be recorded and may be applied whether pre-qualification under *Rule 15* has or has not been done.

The best ranked bid submitted by (*insert name of company*) was subjected to qualification examination covering (*add/delete, as applicable*):

11. experience and performance on similar contracts
12. equipment and manufacturing/construction facilities
13. qualifications and experience of personnel
14. financial position
15. local facilities and representation
16. current capacity available.

(Record any constraints or limitations, and accept or reject [with full justifications] the bidder.)

(If the bidder is rejected, repeat the qualification test for the next ranked bidder.) (*Insert name of company*) is confirmed to have passed the qualification requirements. The original estimated market price of the procurement was (*insert amount*).

Recommendation

Based on the evaluation criteria stated in the bidding document, it is recommended that the award be made to (*insert name of company*), for a total contract value of (*insert currency and amount*), for the procurement of (*list all items that the award relates to*). (Or, recommend negotiations with the recommended company and state the purpose of negotiations.)

Signed by the Technical (Evaluation) Committee:

Signature:…….. Name:…….

Signature:…….. Name:…….

Signature:…….. Name:…….

Date:……..… (DD/MM/YY)

Attachments: (where applicable)

List of bidders who purchased or received the bidding documents:

Record of bid opening:

Record of samples received:

Bid opening attendance list:

Evidence of exchange rates used for conversion to Pakistani rupees:

Summary of Technical Evaluation

(Only bids that were responsive)

Form SPF 4

Procurement Number					
Agency	**Department/ Project**	**Financial Year**	**Sequence Number**	**Bid Number**	**Contract Number**

No	**Bidder**	**Technical Compliance**	**Comments (reasons for non-compliance)**
1		C/NC	
2		C/NC	
3		C/NC	
4		C/NC	
5		C/NC	
6		C/NC	

Key: **C** Denotes compliant **Nc** Denotes non-compliant

This examination eliminated (*insert number*) bidders: (*insert names of bidders*).

List names of bidders eliminated on separate sheet(s).

If technical evaluation is complex, attach combined technical specification and compliance sheets for each quotation/tender.

Summary of Price Evaluation

(Only bids that are responsive and technically compliant)

Form SPF 4

Procurement Number					
PA	**Department/ Project**	**Financial Year**	**Sequence Number**	**Bid Number**	**Contract Number**

No.	Bidder	Amount of Bid and Currency	Corrections to Bid Price	Exchange Rate	Amount in Pakistani Rupees	Adjustments to Bid Price	Evaluated Bid Price	Rank
1								
2								
3								
4								
5								
6								
7								
8								

Annexure 48: Request for Evaluation Report Approval

(Extracted from *Manual of Procurement Policies and Standard Operating Procedures for the NHF Programs of the former Ministries of Health and Population Welfare, Government of Pakistan*)

Name of Procuring Agency: Form SPF 2

Submission to Relevant Authority

Request for Approval of Evaluation Report

Procurement Number					
Entity	Department/ Project	Financial Year	Sequence Number	Bid Number	Contract Number

Subject of Procurement:	

No	Bidder	Amount of Bid and Currency
1	Type of evaluation report (technical only or combined financial and technical)	
2	Have negotiations been held with the recommended bidder or other bidders? If yes, give details.	
3	Name and address of supplier/contractor recommended for contract award:	
4	Currency and total amount of recommended contract award:	
5	Any other relevant information:	

Documents Attached: (List any other documents or delete if not applicable)

17. Evaluation report for goods
18. Record of negotiations, if applicable
19. Copies of all bids submitted.

Related documents previously submitted: (Available for reference from the secretariat to the tender committee)

20. Approved bidding document

Previous submission: *(Section letter and title)*		**Date approved:**	

The information contained in this form and the attached documents is complete, true, and accurate, and in accordance with the procurement manual and standard bidding documents.

Signature:_____ Name:_____

Position:_____ Date: _____

Responsible Officer (dd/mm/yyyy)

Annexure 49: Recommendation for Contract Award

(Extracted from *Manual of Procurement Policies and Standard Operating Procedures for the NHF Programs of the former Ministries of Health and Population Welfare, Government of Pakistan)*

Name of Procuring Agency Form SPF 2

Submission to Relevant Authority

Recommendation for Contract Award

Procurement Number					
Entity	Department/ Project	Financial Year	Sequence Number	Bid Number	Contract Number

Subject of Procurement:	

SUBMISSION INFORMATION		
1	Name and address of Supplier/Contractor	
2	Total value of Contract	
3	Proposed date of contract signature	
4	Any other relevant information	

Documents Attached: (List any other documents or delete if not applicable)

1. Draft Contract
2. Draft Notice of Award

Related Documents Submitted Previously: (Available for reference from the Secretariat to the Tender Committee)

1. Approved Bidding Document
2. Approved Evaluation Report

Previous Submission: *(Section letter and title)*		**Date Approved:**	

The information contained in this form and the attached documents is complete, true and accurate and in accordance with the Procurement Manual and Standard Bidding Documents.

Signature:_____ Name: _____

Position:_____ Date:_____
Responsible Officer (DD/MM/YY)

Annexure 50:
Contract Award Pro Forma I

Khyber Pakhtunkhwa Public Procurement Regulatory Authority (KPPRA)

To be completed (filled in) and uploaded on the KPPRA website for all public contracts of works, services, and goods.

Name of the organization/department: _____

Federal/provincial government: _____

Title of contract: _____

Tender number: _____

Brief description of contract: _____

_____

_____

_____

Tender value: _____

Estimated completion period: _____

Was the procurement included in annual procurement plan? _____

Yes/No

Advertisement:

KPPRA website: _____ Yes/No (federal agencies) (If yes, give date and KPPRA's tender number)

Newspapers: _____ Yes/No (If yes, list names of newspapers and dates)

Tender opened on (*insert date and time*): _____

Nature of purchase: _____

Local/international: _____

Extension on due date (if any): _____ Yes/No

* Number of tender documents sold:_____
(*Attach list of buyers*)

Was the qualification criteria included in bidding/tender documents?
_____Yes / No

(If yes, enclose a copy)

Was the evaluation criteria included in bidding/tender documents?
_____Yes / No

(If yes, enclose a copy)

Which method of procurement was used? (check one)

(a) Single-stage—one-envelope procedure: _____

(b) Single-stage—two-envelope procedure: _____

(c) Two-stage bidding procedure:_____

(d) Two-stage—two-envelope procedure:_____

- Please specify if any other method of procurement was adopted, including a brief explanation (i.e., emergency, direct contracting, negotiated tendering, etc.).
- Who is the approving authority?_____

Was approval of the competent authority obtained using a method other than open competitive bidding? yes/no

Number of bids received: _____

Was the successful bidder the lowest bidder?_____ yes/no

Was the integrity pact signed? _____yes/no

Annexure 51:
Contract Award Pro Forma II

Khyber Pakhtunkhwa Public Procurement Regulatory Authority (KPPRA)

To be completed (filled in) and uploaded to the KPPRA website for all public contracts of works, services, and goods.

Number of bidders present when the bids were opened:

Name and address of the successful bidder:

Ranking of successful bidder in evaluation report (i.e., 1st, 2nd, 3rd evaluated bid):

Needs analysis (Why was the procurement necessary?):

If extension was made in response time, what were the reasons (briefly describe):

Annexure 52: Sample Format for Notification of Acceptance

Memo No._____ Date_____

Government of Khyber Pakhtunkhwa

Population Welfare Department

(Mention address)

To

M/S *(mention name and address of the bidder)*

Subject: Award Notification against bid package no.____ for supplying*(mention short description of goods)*

Dear Sirs,

We are pleased to award you the contract for bid package no. *(mention no.)* forthe goods and price as mentioned below:

Bid Package No. and short description of goods	Total Contract Price with Currency	Basis of Contract
(mention short description of goods)	*(mention price with currency)*	*(mention whether it is a CIF,CFR or EXW contract or otherwise)*

Please note that the contract will include, among others, the following documents:

i) The Form of Contract,

ii) The Bid Form and the Price Schedule submitted by the Bidder,

iii) The Schedule of Requirements (offered by the Bidder and accepted by the Purchaser),

iv) The Technical Specifications (offered by the Bidder and accepted by the Purchaser),

v) The General Conditions of Contract,

vi) The Special Conditions of Contract (duly filled in), and,

vii) The Performance Security submitted by the Bidder.

Two copies of the contract form are enclosed herewith for your signing and returning to us. Please also submit a Performance Security in the amount not less than *(mention percentage) of the contract price* within *(mention number of days)* of receipt of this award notification.

Annexure 53:
Sample Instructions for Letter of Credit Application

Instructions for Letter of Credit Application

Date: _____

Attention: (Finance unit or department that handles letter of credit requests)

Reference: (Contract or purchase order number)

Please instruct our bank to open an irrevocable, confirmed, documentary letter of credit as follows:

1. Beneficiary: _(seller's name and address)

_____

2. Advising bank: ____ (bank's name and address)

3. Letter of credit amount: _____

4. Shipping terms: _____

5. Shipment via: _____

6. Shipping date: _____

7. Letter of credit expiration date:

8. Shipment from: _____

9. Shipment to: _____

(Port or airport, city, and country of final destination)

10. Merchandise description:

11. Merchandise value: _____
(Include any down payments not included in the letter of credit amount.)

12. Partial shipment: _____ not allowed _____ allowed

13. Trans-shipment: _____ not allowed _____ allowed

14. Documents required:

This requirement varies from country to country. Please review your country's import requirements, as well as your own agency's requirements. Typical shipping document *for air freight* shipments are included below:

- Commercial invoice (state number of each required):

  _____ originals _____ copies

- Packing list (state number of each required):

  _____ originals _____ copies

- Original air waybill (state number of each required) consigned to:

  _____

  _____ originals _____ copies

- Insurance certificate for 110% of CIP value (state number of each required)

  (Insure for total cost of commodities, transportation, and insurance, plus minimum of 10 percent. Total cost of commodities includes down payment to supplier not included in L/C amount.)

  _____ originals _____ copies

Insurance payable to: _____

- Certificate of conformity with contract specifications issued by _____ _____ (*insert name of third party inspection agent*).

- Beneficiary's signed certification that the following documents were sent with the shipment (*insert list of required documentation*).

  _____

  _____

- Beneficiary's signed certification that all the shipping boxes are labeled with the following shipping marks:

15. Special letter of credit/conditions:

16. Letter of credit transmittal method: Airmail: _____ Full text cable: ____Electronic: _____

Annexure 54: Responsibilities for Contract Performance

Responsibilities for Contract Performance (Example)

Supplier

1. Provides performance security.
2. Notifies purchaser, in writing, of all subcontracts awarded under the contract, if not stated in the bid.
3. Provides reasonable facilities and assistance to inspection agents; including, for inspection purposes, access to production data and quality control records.
4. Provides packing sufficient to prevent damage or deterioration of goods during transit.
5. Includes appropriate temperature monitoring devices with packing, if needed.
6. Complies with requested routing.
7. Arranges and pays for shipping and insurance (CIF terms).
8. Notifies purchaser by fax, telex, cable, or email the full details of shipment.
9. Forwards shipping documents and QA documents to purchaser.
10. Delivers goods in accordance with the time schedule of the contract.
11. Requests payment in writing from the purchaser (or purchaser's bank).
12. Pays taxes, stamp duties, license fees, and any other levies imposed outside the destination country (foreign supplier).
13. Pays taxes, duties, and license fees incurred or imposed locally, prior to delivery (local supplier).
14. Replaces rejected goods.
15. Notifies purchaser, in writing, of any impending delay in delivery, the likely duration, and the cause.
16. Claims any adjustment in price within 30 days after receipt of change order.
17. Notifies purchaser in writing of any force majeure situation.

Purchaser

1. Opens letter of credit in favor of supplier.
2. Arranges and prepares for pre- and post-shipment inspections and tests.
3. Pays for pre-shipment inspections and tests.
4. Notifies supplier (in writing) of any representatives retained for inspections and tests.
5. Authorizes (in writing) shipment of goods, based on pre-shipment inspection and test results.
6. Provides transportation of goods after delivery.
7. Arranges for payment of contract price to supplier upon receipt of invoice and documents.
8. Provides acceptance certificate for each delivery.
9. Discharges and returns performance security to supplier not later than 30 days following the date of completion of the supplier's performance obligation, including any warranty obligation under the contract.
10. Notifies supplier (in writing) of any claims arising under warranty.
11. Issues change orders (in writing) to supplier for any modification to specifications, method of shipment, place of delivery, or services.
12. Notifies supplier (in writing) of default(s).
13. Notifies supplier (in writing) of intention to terminate contract, for any reason.

Annexure 55:
Estimated Schedule for Contract Performance and Shipping

Sample Contract Performance Timeline

Task Name	Resource Name	Month 1	Month 2	Month 3	Month 4	Month 5	Month 6
Sign Contract	Supplier						
Arrange Performance Security	Supplier						
Open Letter of Credit	Purchaser						
Production Period	Supplier						
Arrange Inspection and Testing	Purchaser						
Pre-shipment Inspection and Test							
Authorize Shipment	Purchaser						
Arrange Shipment and Insurance	Supplier						
Notify Shipping Details	Supplier						
Forward Shipping Documents	Supplier						
Shipping Period							
Delivery Date							
Customs Clearance	Purchaser						
Receiving Inspection	Purchaser						
Release							

Annexure 56: Sample Shipping and Marking Instructions

Shipping Instructions

To:_____*(insert supplier's name)*

Contract No.: _____

For Shipment(s) to Consignee/Purchaser

(Department of Population Welfare, Government of Khyber Pakhtunkhwa)

Prior to Shipment of Commodities

21. Contact _____(insert name and address of contracted inspection agent/company)

Upon Receipt of Authorization for Shipment

22. Assemble packed, marked, inspected, and approved unit packages on a pallet base selected to best utilize the space of a standard 20-foot shipping container. Use horizontal and vertical strapping to secure the load tightly and firmly, without an overhang. Plastic shrink wrap can be used to stabilize and protect palletized loads.
23. Arrange for a sufficient number of standard 20-foot containers to accommodate the shipment. Goods may not be consolidated with other freight.
24. Prior to loading, shipping containers must be inspected for cleanliness, safety (free from splinters, snags, dents, or bulges), security (door gaskets, seals, hardware, fittings, etc.), watertight integrity, and overall container seaworthy condition. Contents shall be verified and containers sealed in the presence of an insurance surveyor. A written surveyor's report attesting to the above conditions is required.
25. Load containers to the optimum degree possible without damaging the shipping cartons. Fill all voids by bracing or using fillers to prevent sliding or shifting of cargo. Provide plastic or water-repellent shrouds over the top and sides of the load to protect against damage from condensation, which may accumulate on the interior container surfaces.
26. Ship in standard 20-foot containers via ocean freight on the flag vessel of _____(*insert country*), to _____(*insert name and address of consignee including city and country*)
27. Commodities must be insured for 110 percent of their total CIF value, covering all risks from warehouse to port of unloading.
28. Do not ship freight *collect*. Freight must always be *prepaid*.
29. Documentation requirements are as follows:

- commercial invoice
- packing list
- bill of lading
- Certificate of Origin

- Insurance Certificate
- Certificate of Analysis
- Societie General Surveillance (SGS) Clean Report of Findings
- Insurance Surveyor's Report.

30. The commercial invoice must state the—

- name and address of supplier/shipper
- name and address of consignee
- invoice number
- date of invoice
- letter of credit
- contract number
- place and date of shipment
- number of shipping cartons
- weight of each shipping carton
- number of pallets' number of shipping cartons per pallet
- number of containers; number of pallets per container
- lot number(s) and quantities shipped
- complete description of product, including expiry date
- unit price of product
- total FOB value of shipment
- freight and insurance charges
- total CIF value of shipment
- gross weight of shipment
- country of origin.

Marks:_____(*insert*)

Port of destination: _____ (*insert*)

Notify consignee upon arrival at _____ (*insert telephone number*)

31. The bill of lading must include container number(s), contract number, letter of credit number, and country of origin, in addition to standard bill of lading information requirements.
32. Send to _____(*insert consignee's name)* via special courier, two sets of the following shipping documents (copies are acceptable if originals are required by bank for payment under the L/C):

- signed commercial invoice
- packing list
- bill of lading
- Certificate of Origin
- insurance certificate
- Certificate of Analysis
- Societie General Surveillance (SGS) Clean Report of Findings
- insurance surveyor's report.

33. At least seven days before shipment, advise_____(*insert consignee's name*) via fax or email the—

- contract number

- vessel's name and voyage number
- booking number
- container number(s)
- estimated departure date and estimated date and estimated time of arrival (ETA) at _____ (*insert port of destination*).
- bill of lading number
- quantity of product shipped
- number of shipping cartons
- number of containers
- weight and total value of shipment.

Annexure 57: Sample Inspection Order

Sample Inspection Order

To: _____ (insert name of inspection agent/company)

Date:

Contract number:

Vendor: XYZ Corporation (*insert name of vendor*)

Consignee: PWD, Government of Khyber Pakhtunkhwa

Inspection Order

Inspect packing and marking for compliance with section _____ of attached technical specifications.

Conduct inspection in accordance with ISO 2859-1, Inspection by Attributes Inspection level shall be S-3 with an acceptable quality level (AQL) of 2.5 percent:

For exterior shipping cartons, the lot size shall be the number of exterior shipping cartons; the sample unit shall be one exterior shipping carton.

For other levels of packing, the lot size shall be the number of inner boxes; the sample unit shall be one inner box.

1. Inspect and score for defects as follows:

	Defects*
Contents	Quantity of goods not as specified; packets or strips not as specified
Marking	Omitted; incorrect; illegible; of an improper size, location, sequence, or method of application
Materials	Packaging/packing materials not as specified, missing, damaged, or not serviceable
Workmanship	Shipping cartons inadequately closed and secured; poor application of internal packaging and packing material; distorted inner boxes

* Examination of defects of closure shall be performed on units fully prepared for delivery.

a. Exterior shipping cartons selected at random from lot proposed for delivery.
b. Inner boxes selected at random from sample shipping cartons.

2. Examine documentation

   Refer to attached shipping instructions and confirm all documents listed are complete.

   Confirm that values appearing on certificates of analysis for the lot(s) prepared for shipment are within the range mentioned in the product's National Regulatory Authority (NRA) dossier and/or specified in the relevant pharmacopoeia, per the procurement specification.

3. Provide a written report for approval by the Government of Pakistan (GOP) on packing and marking, and documentation, prior to release of a clean bill of goods.

4. Unless otherwise specified in writing, the inspection agent is not authorized to sign the *Authorization for Shipment* form.

Annexure 58: Sample Authorization for Shipment

Authorization for Shipment

Attn: _____ [supplier's name]

Ref: Contract Number _____

Letter of Credit Number _____

Authorization for Shipment

Re: _____ [description of goods]

Pre-shipment inspection and test data have been received and approved by:

_____ [Purchaser]

Signature

Signature of this document by the authorized representative indicates that the commodity conforms to the Contract Number_____ and is released for shipment.

This certificate does not release supplier from compliance with warranties and other conditions included in this contract.

Authorized Representative

Date

Appendix

Appendix 1:

The Khyber Pakhtunkhwa Public Procurement of Goods, Works and Services Rules 2014

GOVERNMENT OF THE KHYBER PAKHTUNKHWA

FINANCE DEPARTMENT

NOTIFICATION

Peshawar, Dated the 3rd February, 2014

No. SO(FR)/FD/9-7/2010/Vol-II: In exercise of the powers conferred by section 36 of the Khyber Pakhtunkhwa Public Procurement Regulatory Authority Act, 2012 (Khyber Pakhtunkhwa Act No.XI of 2012), the Government of the Khyber Pakhtunkhwa is pleased to make the following rules, namely:

The Khyber Pakhtunkhwa Public Procurement of Goods, Works and Services Rules, 2014.

CHAPTER 1

GENERAL PROVISIONS

1. Short title and commencement.-- (1) These rules may be called the Khyber Pakhtunkhwa Public Procurement of Goods, Works and Services Rules, 2014.

(2) These shall come into force at once.

2. Definitions.-- (1) In these rules, unless there is anything repugnant in the subject or context,-

(a) "Act" means the Khyber Pakhtunkhwa Public Procurement Regulatory Authority Act, 2012;

(b) "bid" means a technical proposal or a financial proposal or a technical and financial proposal submitted as a result of request for quotations, tender notice, request for proposal as the case may be;

(c) "bid security/ surety/ guarantee" means a written guarantee from a third party guarantor usually a bank or an insurance company submitted to a client by a contractor or bidder with a bid;

(d) "borrower" means procuring entity;

(e) "contractor" means a person, a firm, a company or an organization undertaking supply of goods, works or non consulting services;

(f) **"**emergency**"** shall refer to situation that poses an immediate risk of loss, or has caused loss, or has high probability of escalating to cause immediate danger to health, life, property or environment as covered under the National Disaster Management

Act, 2010 (Act No. XXIV of 2010) and shall include natural calamities, disasters, accidents, war and breakdown of operational equipment, plant, machinery or engineering infrastructures, which may give rise to abnormal situation requiring prompt and immediate action to limit or avoid damage to health, life, property or the environment;

(g) "grievance redressal mechanism" means the regulations/guidelines providing for grievance redressal process;

(h) "non -consulting services" means the provision of independent expert advice of a quality at least equal to the applicable professional standards in relation to acquisition of goods, services other than consulting services and works;

(i) "PEC" means Pakistan Engineering Council;

(j) "professional engineering work" means providing professional advice and opinions, the making of measurements and layouts, the preparation of reports, computations, designs, drawings, plans, specifications and construction, inspection, and supervision of engineering works, in respect of:

(i) railways, aerodromes, bridges, tunnels and roads;

(ii) dams, canals, rivers, drains, harbors, lighthouses;

(iii) works of an electrical, mechanical, hydraulic, communication, aeronautical, power engineering, geological or mining character;

(iv) water works, sewers, filtration, purification and incinerator works;

(v) residential and non-residential buildings including foundations framework and electrical and mechanical systems thereof; and

(vi) structures accessory to engineering works and intended to house them;

(k) "Province" means the Province of the Khyber Pakhtunkhwa;

(l) "Public Fund" 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;

(m) "repeat order" means a fresh contract or order given directly to the same contractor or consultant without going into the normal procurement process, in accordance with the specified conditions and limits contained in these rules;

(n) "request for proposal" means bidding document for soliciting technical and financial proposals for procurement of services;

(o) "supplier" means a person, a firm, a company or an organization undertaking supply of goods, services or works;

(p) "terms of reference" means defining and elaborating on the objectives and intended scope of services; and

(q) **"**value for money**"** means best returns for each rupee spent in terms of quality, timeliness, reliability, after sales service, up-grade ability, price, source, and the combination of whole-life cost and quality to meet the procuring entity's requirements.

(2) Words, expressions and terms not specifically defined in these rules shall have the same meanings as attributed to them in relevant trade and industry practices.

3. Applicability of these rules.— (1) These rules shall be applicable to all public procurements.

(2) Under following circumstances deviation from the requirements of advertisement and response time under these rules is permissible:

(a) in cases of emergency as provided in the National Disaster Management Act, 2010 (Act No. XXIV of 2010), subject to the condition,--

(i) that all such procurements along with its emergent nature has to be recorded by the Procuring Officer and approved by the technical head of the procuring entity under intimation to the Principal Accounting Officer, Secretary at Provincial or Deputy Commissioner at District level;

(ii) that these have to be immediately intimated to the Accountant General Office or District Accounts Office, as the case may be;

(iii) that quantities in all such procurements shall be limited to the assessed requirement of emergency only; and

(iv) that these shall be used only for procurements upto maximum for three months, which may be extended for such a period that Government may deem fit, depending on the nature of emergency;

(b) the procurement of sensitive nature and related to National Security:

Provided that the direct sourcing of all such procurements shall be duly recorded; and

(c) the direct sourcing to a government organization for provision of works, goods or services under a cost plus or fixed contract provided that the Public Sector Organization shall not involve a private sector enterprise as a partner or in the form of a joint venture or a sub-contractor. The government organizations shall be totally government owned and controlled or semi-autonomous and autonomous agencies under the administrative control of Federal Government or Provincial Government.

4. Language.—All documentation related to public procurements of entities shall be in English or Urdu.

5. Code of ethics and integrity pact.---Procurement exceeding the prescribed limit shall be subject to an integrity pact, as specified by regulations/guidelines determined by Authority in consultation with procuring entities, between the procuring entity and the suppliers or contractors.

CHAPTER II

METHODS OF PROCUREMENT OF GOODS

6. Open tendering open competitive bidding as principal method of procurement.-- (1) Save as otherwise provided hereinafter and subject to the provisions of rule 10, the procuring entity shall use open competitive bidding as the principal method of procurement for the procurement of goods over the value of Rs. 100,000 (rupees one hundred thousand).

(2) The following procedures shall be permissible for open tendering, namely:

a) *single stage, one envelope procedure*.-- this method should be used where cost is the only determining factor. Each bid shall comprise one single envelope containing financial proposal or offer and required information in accordance with the bid solicitation documents. This shall be the standard method of procurement of goods for simple and routine nature and where no technical innovation is involved;

b) *single stage, two envelops procedure.*-- this method shall be used where bids are to be evaluated on technical and financial grounds and price is taken into account after technical evaluation. Bid shall comprise a single package containing separate envelopes. Each envelope shall contain separately the financial proposal and technical proposal;

(3) In case of procurement of complex or specialized goods either of the two methods may be adopted,--

(a) pre-qualification of prospective bidders and invitation of bids from the pre-qualified bidders; and

(b) through single envelope two stage method post-qualification-

(i) in the first stage, each bid shall comprise of a single package containing envelope marked as technical proposal;

(ii) the technical proposals will be evaluated in accordance with the evaluation criteria set forth in the bid solicitation document. A list of qualified and unqualified bidders will be formulated at the end of first stage;

(iii) following approval of the results of first stage, financial proposals will be solicited from qualified bidders in the second stage. The bidders will be required to submit financial proposal in a single envelope or package clearly marked as financial proposal in bold and legible letters to avoid confusion; and

(iv) the lowest offer from the qualified bidder shall be accepted for award of the contract and will be the best evaluated bid.

7. Enlistment of suppliers.-- (1) A procuring entity may establish a mechanism for enlistment of suppliers for the purposes of procurement of goods and related services only in exceptional or complex cases where specialized goods, equipment and related services are required.

(2) The process of enlistment with such departments shall be open to all prospective bidders. Annual renewal for all such pre-registrations or enlistment shall be done on regular basis.

(3) The enlistment forms shall be made available at the department's and authority's websites in addition to all possible outlets at nominal or preferably no cost.

(4) The enlistment or renewal with the relevant department shall be undertaken by a committee with five members with the chairperson being an officer of not less than BPS-19. Results showing the latest enlisted or renewed suppliers, those having rejected along with the recorded reasons for their rejection shall be made public within five days after the committee has concluded business in this regard.

(5) Enlistment shall not be deemed as pre-qualification or post-qualification.

8. Pre-qualification of suppliers.--(1) A procuring entity, in the first stage may pre-qualify bidders only in the following cases:

(a) where total worth of contract exceeds Rs. 10 million; and

(b) in cases of contracts for large and complex goods and related services, in which there are high costs of preparing detailed bids.

(2) The procuring entity may pre-qualify bidders by soliciting various details in accordance with sub-rule (1) of rule 8, and rule 36 of these rules.

(3) Pre-qualification of bidders shall be based entirely upon the capability, competence and resources of the bidders relevant to performance in the particular assignment, taking into account the following--

(a) legal status along with proof of registration with one of the Federal or Provincial Registration Acts;

(b) proof of being a taxpayer;

(c) organizational profile, relevant experience, past performance, list of clients and references;

(d) relevant experience and past performance;

(e) existing capabilities with respect to human resource, personnel, computing and engineering equipment, machinery and plant, as may be the case;

(f) financial position for the last three years including bank statements and audited reports by an external auditor;

(g) proof of possessing appropriate managerial capability; and

(h) any other factor that a procuring entity may deem relevant, depending on the nature and complexity of the contract but not inconsistent with these rules.

(4) Qualified bidders shall be issued the tender documents.

(5) For further process sub-rule (2) of rule 6 shall be followed.

9. Open tendering post-qualification.--(1) If bidding is not limited to pre-qualified firms, the procuring entity shall engage itself in post qualifying the bidders , in case of contracts of complex nature and valuing Rs. 15 million or above.

(2) Procuring entity shall specify the requirement of post-qualification in the solicitation documents. Post-qualification may be undertaken in accordance with the provision of these rules, regardless of the bidders being pre-qualified.

(3) This shall be done prior to recommending contract award; the procurement committee shall determine whether the bidder whose bid has been determined to offer the best evaluated bid has the capability and resources to effectively carry out the contract offered in the bid.

(4) In case the procurement committee is not satisfied with qualification based on the evaluation criteria resulting is not post-qualifying the best evaluated bid, it shall proceed to make a similar determination for the bidder offering the next best evaluated bid and shall go on with all the qualified and responsive bidders in accordance with their ranking in being best evaluated, till the criteria is satisfied or till all such bids are rejected.

10. Alternate methods for procurement of goods.---A procurement entity may use the following alternative methods for procurement of goods, namely:

(a) procurement of goods upto Rs. 50,000/- may be undertaken by obtaining a single quotation through direct sourcing.

(b) petty purchases between Rs. 50,000/- upto Rs. 100,000/- shall be procured through alternate method only if the following conditions are met, namely:

(i) minimum of three quotations have been obtained:

Provided that if despite soliciting, less than three quotations are received it would be acceptable;

(ii) request for quotation is sent to prospective bidders, simultaneously, with full contents and same information, which is duly acknowledged to be received;

(iii) the closing time, date and address for submitting quotations has been clearly defined and adhered to;

(iv) the object of the procurement has standard specifications;

(v) in case, amount pertaining to applicable tax is not added in the quotation, comparison of price is made after adding amount of applicable tax; and

(vi) during comparison, each item should be compared to the corresponding respective specification and bid evaluated to the corresponding total cost of the bid;

(c) a procurement entity shall only engage in alternate method if the following conditions exist, namely:

(i) repeat orders within a period of six months:

Provided that it does not exceed fifteen percent of the original contract value;

(ii) in case of procurement through government organizations, in accordance with provisions of rule-3(2)(c) of these rules;

(iii) where the procurement concerns the acquisition of spare parts or supplementary services from original manufacturer or supplier or sole distributor:

Provided that the same are not available from alternative sources;

(iv) where the same goods are not available from alternative sources or only one contractor, manufacturer or supplier exists for the required procurement;

(v) where a change of contractor or supplier would ensue the procuring entity to acquire material having different technical specifications or characteristics and would result in incompatibility or disproportionate technical difficulties in operation and maintenance, this shall be done with proper justification and

recording of such reasons, provided that the contract or contracts do not exceed three years in duration;

(vi) where the price of goods is fixed by Government;

(vii) where the motor vehicles or machinery is purchased from local original manufacturers or their authorized agents at manufacturer's price including transportation charges and other applicable taxes; and

(viii) in case of emergency as defined in these rules and procurement specified under sub-rule 3(2)(a) and 3(2)(b):

Provided that the procurement entity shall specify appropriate forums vested with necessary authority to declare an emergency;

(d) a procuring entity may engage in negotiated tendering with one or more suppliers or contractors without prior publication of a procurement advertisement. This procedure shall be followed when--

(i) the supplies involved are manufactured purely for the purpose of supporting a specific piece of research or an experiment, a study or a particular development;

(ii) for technical or artistic reasons, or for reasons connected with protection of exclusive rights or intellectual property, the supplies may be manufactured or delivered only by a particular supplier; and

(e) for reasons of extreme urgency brought about by events unforeseeable by the procuring entity, the time limits laid down for open and limited bidding methods cannot be met. The circumstances invoked to justify extreme urgency must not be attributable to the procuring entity:

Provided that any procuring entity desirous of using negotiated tendering as a method of procurement shall record its reasons and justifications in writing for resorting to negotiated tendering and shall place the same on record.

11. Method of advertisement.---(1) The procurement entity shall engage in open competitive bidding if the cost of the object to be procured is more than the financial limit which is applicable under rule 10 purchases upto Rs. 2.5 million, shall be posted on the procuring entity's website or public procurement regulatory authority (PPRA's) or both. These procurement opportunities may also be advertised in print media, if deemed necessary by the procuring entity.

(2) For all purchases, other than those being covered by the Khyber Pakhtunkhwa Procurement rules 3 and 10, shall be advertised in print media, appearing in at least one national English and one Urdu newspaper with nationwide circulation along with advertising the same either on the procuring entity or Authority website.

(3) A procuring entity utilizing electronic media shall ensure that the information posted on the website is complete for the purposes for which it has been posted, and such information shall remain available on that website until the closing date for the submission of bids.

12. Bid security.---(1) The procuring entity may require the bidders to furnish bid security of up to two per cent in case of procurement of goods, if required.

(2) In cases, where procurement is of complex nature, bid security up to 5 percent can be applied.

(3) Bid security shall be kept sealed in the financial proposal. In case of two stage two envelopes the bidder shall, in addition, keep an affidavit in the technical proposal stating that a bid security amounting to 2,3,4 or 5 percent, as may be the case without indicating the figure in the letter, has been placed in the financial proposal or bid. Otherwise the technical proposal will be considered non-responsive and will be returned to the bidder after being examined by the procurement committee.

13. Goods warranty.--Where possible, the procuring entity shall ask for a warranty from the supplier or contractor, for replacement or repair of the procured goods falling in the warranty period.

CHAPTER III

PROCUREMENT OF WORKS AND NON-CONSULTING SERVICES

14. Open tendering open competitive bidding as principal method of procurement.--

(1) Save as otherwise provided hereinafter and subject to the provisions of rule 10, the procuring entity shall use open competitive bidding as the principal method of procurement for the procurement of goods over the value of Rs. 100,000/ rupees one hundred thousand.

(2) the following procedures shall be adopted for open competitive bidding:

(a) *single stage* – one envelope bidding,--the bid shall comprise of one envelope containing financial bid. All bids received shall be opened and evaluated in the manner prescribed in the bidding document. This shall be the default method of open competitive bidding;

(b) *single stage* – two envelope bidding,--

(i) this method shall apply to large and complex contracts;

(ii) bidders for this method shall be pre-qualified;

(iii) each bid shall comprise a single package containing two separate envelopes. Each envelope shall contain separately the technical proposal and the financial proposal;

(iv) the envelopes shall be marked as technical proposal and financial proposal in bold and legible letters to avoid confusion;

(v) the envelope marked as technical proposal shall contain:

(a) the experience and past performance in the execution of similar contracts;

(b) the capabilities with respect to personnel and construction equipments;

(c) the financial status and capacity; and

(d) any other information asked for by the procuring entity in the notice inviting tenders;

(vi) the second envelope marked as financial proposal shall contain the price quoted by the bidders and be retained in the custody of the procuring entity without being opened;

(vii) the procuring entity shall evaluate the technical proposal on the basis of criteria specified in the tender documents without reference to the price and reject any proposal which does not conform to the specified requirements. During the technical evaluation, no amendment in the technical proposal shall be permitted. A list of technically qualified bidders shall be finalized in this manner;

(viii) after the evaluation and approval of the technical proposals the procuring entity, shall at a time within the bid validity period, publicly open the financial proposals of the technically accepted bids only. The financial proposals 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;

(c) *two stage - two envelope bidding,*---this method shall be used for turnkey or large or complex contracts and ensures that all technical proposals conform to the same acceptable technical standards required by the procuring entity.

First stage:

(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 the procuring entity without being opened;

(v) the technical proposal shall be discussed with the bidders with reference to the procuring entity's technical requirements;

(vi) those bidders willing to meet the requirements of the procuring entity shall be allowed to revise their technical proposals following these discussions; and

(vii) bidders not willing to conform their technical proposals to the revised requirements of the procuring entity shall be allowed to withdraw their respective bids without forfeiture of their bid security.

Second stage:

(i) after agreement between the procuring entity and the bidders on the technical requirements, bidders who are willing to conform to the revised technical specifications and whose bids have not already been rejected shall submit a revised technical proposal and supplementary financial proposal, according to the technical requirement;

(ii) the revised technical proposal along with the original financial proposal and supplementary financial proposal shall be opened at a date, time and venue announced in advance by the procuring entity:

Provided that in setting the date for the submission of the revised technical proposal and supplementary price proposal, a procuring entity shall allow sufficient time to the bidders to incorporate the agreed upon changes in the technical proposal and to prepare the required supplementary financial proposal; and

(iii) the procuring entity shall evaluate the whole proposal in accordance with the evaluation criteria and the bid found to be the lowest evaluated bid shall be accepted.

15. Enlistment.—(1) Enlistment shall not be deemed as pre-qualification or post-qualification.

(2) The process of enlistment shall be open throughout the year and any prospective bidders shall be allowed to apply for without any hindrance.

(3) Procuring entities shall decide the applicable nominal fee and the period of such pre-registrations, after which a renewal shall be necessary.

(4) Such enlistment/renewal with the relevant department shall be undertaken by a committee with five members with the chairperson being an officer of not less than BPS-19. Results showing the latest registered/renewed suppliers, those having rejected along with the recorded reasons for their rejection shall be made public within five days after the committee has concluded business in this regard.

(5) Criteria for enlistment shall be based on the evaluation of technical and financial worth i.e. works executed, indicating value of works, list of technical and other staff, plant/equipment along with the made and financial capacity.

(6) The criteria and list of enlisted bidders shall be posted on the department and Authority web-sites as well as on a notice board placed in the respective departments at an accessible site for public viewing.

(7) Bidding may be limited to enlisted bidders.

16. Pre-qualification of contractors.--(1) A procuring entity, in the first stage shall pre-qualify bidders for specific contracts in cases where total worth of contract exceeds Rs. 45 Million or a work irrespective of its worth is considered as complex.

(2) The procuring entity shall pre-qualify bidders by soliciting various details including but not limited to the following providing pass/fail thresholds, in accordance with the provisions of the Act and rules 17(1) and 34 of these rules.

(a) legal status along with proof of registration with PEC and enlistment with the concerned provincial Government PE;
(b) proof of valid or renewed relevant registration;
(c) proof of being a taxpayer;
(d) organizational profile, relevant experience, past performance, list of clients and references;
(e) existing capabilities with respect to technical personnel, computing and engineering equipment, machinery and plant as may be the case;
(f) financial position for the last three years including bank statements and audited reports by an external auditor;
(g) proof of possessing appropriate managerial capability; and
(h) any other factor that a procuring entity may deem relevant, and is duly included in the bid solicitation documents, depending on the nature and complexity of the contract but not inconsistent with the Act and these rules.

(3) Bidding shall be limited to pre-qualified firms.

(4) Qualified bidders shall be issued the tender documents.

(5) For further process sub-rule (2) of rule 6 shall be followed.

17. Open tendering post-qualification of contractors.--- (1) In case of contracts costing between Rs. 2.5 million to Rs. 45 million, the procuring entity may choose to call for bids with the condition of post-qualification provided in the bidding documents.

(2) The post-qualification criteria provided in the bidding documents shall be based on the evaluation of technical and financial worth i.e. works executed, indicating value of works, list of technical and other staff, plant or equipment along with the make and financial capacity.

(3) Bidding documents shall be made available to all interested bidders.

(4) The qualification of the lowest evaluated responsive bidders shall be checked to ensure whether or not the bidder is qualified to perform the works.

(5) If the lowest evaluated responsive bidder is not found to be qualified on all the post-qualification criteria provided in the bidding documents, its bid shall be rejected.

(6) Credentials of the next lowest evaluated responsive bidders shall then be checked against all of the post-qualification criteria provided in the bidding documents, and the contract shall be awarded to the lowest evaluated responsive qualified bidder.

18. Alternate methods for procurement of works, and non-consulting services.--A procurement entity may use the following alternative methods for procurement, namely:

(a) petty purchases**,--** procurement of upto Rs. 50,000/- may be undertaken by obtaining a single quotation through direct sourcing;

(b) request for quotations,-- procurement from Rs. 50,000/- upto Rs. 100,000/- shall be procured through alternate method only if the following conditions are met, namely:

(i) minimum of three quotations have been obtained, provided that if despite soliciting, less than three quotations are received it would be acceptable;

(ii) request for quotation is sent to prospective bidders, simultaneously, with full contents and same information, which is duly acknowledged to be received;

(iii) the closing time, date and address for submitting quotations has been clearly defined and adhered to;

(iv) the object of the procurement has standard specifications;

(v) in case, amount pertaining to applicable tax is not added in the quotation, comparison of price is made after adding amount of applicable tax; and

(vi) during comparison, each item should be compared to the corresponding respective specification and bid evaluated to the corresponding total cost of the bid;

(c) Direct contracting,-- a procurement agency shall only engage in alternate method if the following conditions exist, namely:

(i) where civil works are to be contracted and are a natural extension of an earlier or ongoing job and it can be ascertained that the engagement of the same contractor will

be more economical and will ensure compatibility of results in terms of quality of works subject to limitation of repeat or variation order;

(ii) in case of procurement through government organizations, in accordance with provisions of rule-3(2)(c) of these rules;

(iii) where a change of contractor or supplier would oblige the procuring entity to acquire material having different technical specifications or characteristics and would result in incompatibility or disproportionate technical difficulties in operation and maintenance, this shall be done with proper justification and recording of such reasons, provided that the contract or contracts do not exceed three years in duration;

(iv) in case of emergency as defined in these rules and procurement specified under sub-rule 3(2)(a) and 3(2)(b), provided that the procurement entity shall specify appropriate forum vested with necessary authority to declare an emergency;

(v) subject to the conditions of contract, a procuring entity may, insure a variation order to a contractor to include works which were outside the original scope of works to ensure interests of Government and for reasons of economy, compatibility and efficiency provided that:

(a) the original contract is still in force;

(b) the procuring entity has satisfied itself for technical reasons that the placing of the variation order is cost effective;

(c) the value of variation order is not more than fifteen percent of the original contract; and

(d) there may be more than one variation orders as long as the total value of all the variation orders remains within 15 percent of the original contract.

19. Method of advertisement.--(1) The procurement entity shall engage in open competitive bidding if the cost of the object to be procured is more than the financial limit which is applicable under rule 10. Procurement from Rs. 100,000/- to Rs. 2.5 million shall be posted on the procuring entity's website or Authority website or both. These procurement opportunities may also be advertised in print media, if deemed necessary by the procuring entity.

(2) For all procurement, other than those being covered by rule 10 shall be advertised in print media, appearing in at least one national English and one Urdu daily newspaper with nationwide circulation along with advertising the same either on the procuring entity or Authority website or both.

(3) A procuring entity utilizing electronic media shall ensure that the information posted on the website is complete for the purposes for which it has been posted, and such information shall remain available on that website until the closing date for the submission of bids.

20. Bid security.--(1) The procuring entity may require the bidders to furnish bid security of two per cent in case of procurement of works, if required.

(2) The bid security shall be kept sealed in the financial proposal. In case of single stage two envelopes, the bidder shall in addition, place an affidavit in the technical proposal stating that a bid security amounting to 2 percent without indicating the figure in the letter, has been placed in the financial proposal or bid. Otherwise the technical proposal will be considered non-

responsive and will be returned to the bidder after being examined by the procurement committee.

(3) The bid security will be returned to unsuccessful bidders after signing of the contract with the successful bidder.

(4) The bid security of the successful bidder will be retained in case no performance guarantee is required, however such a condition shall be mentioned in the bidding document. In case performance guarantee is required, bid security shall be released to the successful bidder after he has submitted the performance guarantee in the shape of an irrevocable bank guarantee.

21. Performance guarantee.--The procuring entity may ask for a performance guarantee from the contractor, which shall not exceed 10 percent of the bid value, as would be specified in the standard bid solicitation documents or standard bidding document.

CHAPTER IV

PROCUREMENT OF CONSULTANCY SERVICES

22. Application of consultancy services rules.--These rules shall apply only to consulting services which are of an intellectual and advisory nature and differ from the other types of services directly connected with the procurement of goods and works in which the physical component of the activity is the main function and often involves equipment-intensive assignments.

23. Systems for selection of consultants.--The selection system shall be determined by the procuring entity prior to the commencement of the process of selection of prospective consultants. Procuring entity may utilize one of the following systems for selection of consultants, namely:

(a) **quality based selection (QBS),--** this system will be used for highly specialized and complex assignments, where quality is the only factor taken into consideration;

(b) **quality and cost based selection (QCBS),---**this system will be used where high quality is the prime consideration while cost is a secondary consideration;

(c) **least cost,---** this system will only be used for assignments of standard or routine nature, where well established practices and standards exist;

(d) **single source or direct selection,---**subject to approval by head of the procuring entity, a procuring entity may engage in single-source procurement-

(i) the goods, construction or services are available only from a particular contractor or supplier, or a particular contractor or supplier has exclusive rights in respect of the goods, construction or services, and no reasonable alternative or substitutes exists; or

(ii) the procuring entity having procured goods, equipment, technology or services from a contractor or supplier, determines that additional supplies must be procured from that supplier or contractor for reasons of standardization or because of the need for compatibility with existing goods, equipment, technology or services, taking into account the effectiveness of original procurement in meeting the needs of the procuring entity, the limited size of the proposed procurement in relation to the original procurement, the reasonableness of the price and the unsuitability of alternative to the goods or services in question; or

(iii) in cases of emergency;

(iv) for very small assignments valuing upto Rs. 500,000/-; and

(v) where only one consultant is qualified or has experience of exceptional worth; and

(e) **fixed budget--** this system shall be used only when the assignment is simple, can be precisely defined and when the budget is fixed. The request for proposals shall indicate the available budget. Proposals that exceed the indicated budget shall be rejected. The ranking shall be based only on evaluation of technical proposals of the qualified bidders.

24. Criteria for eligibility of consultants.--The procuring entity shall not hire a consultant for an assignment in which there is possibility of conflict of interest. If a consultant has been engaged by the procuring entity to provide goods or works for a project, it shall be disqualified from providing consulting services for the same project. Similarly, consultant should not be hired for any assignment which by its nature, may be in conflict with another assignment of the consultant.

25. Expression of interest (EOI).--(1) A request for expression of interest shall be advertised, giving to the applicants at least two weeks for national competition and four weeks for international competition to submit their interest to provide consultancy services.

(2) The expression of interest shall contain at least the following information:

(a) the name and address of procuring entity;

(b) an appropriate description of the assignment providing scope of the intellectual and professional services required;

(c) deadline and place of the submission of expression of interest; and

(d) criteria for short-listing where required.

26. Criteria for short-listing of consultants.--(1) Whenever short-listing is deemed necessary, the procuring entity shall pre-determine criteria for short-listing. Except for single source, there will normally be a minimum of three consultants in the short-list, but there is no upper limit for number of candidates to be short-listed. However, if less than three candidates apply, their proposals may be considered on merit.

(2) The procuring entity while short-listing consultants may take the following factors into consideration, namely:

(a) qualification;

(b) general experience; or

(c) specific experience, particularly of the last five years; or

(d) any other factor that a procuring entity may deem relevant, not inconsistent with these rules.

(3) All applicants shall be informed whether or not they have been short-listed.

27. Request for proposals (RFP).---(1) The procurement entity shall make available to all the short-listed consultants, together with the request for proposals, all information on the equal opportunity basis.

(2) The procuring entity shall use a request for proposal for seeking proposals from the Consultants which shall include the following, namely:

(a) **letter of invitation (LOI),---**the letter of invitation shall mention the name and address of the procuring entity and shall state the intention of the procuring entity to enter into a contract for provision of consulting services;

(b) **instruction to consultants,---**the instructions to consultants shall contain all necessary information that would help them prepare responsive proposals and shall bring as much transparency as possible to the selection system;

(c) **terms of reference (TOR),---**the terms of reference shall unambiguously define the objectives, goals and scope of the assignment besides conditions of contract. Terms of reference shall list the services and surveys necessary to carry out the assignment and expected outputs. It shall also include the evaluation criteria;

(d) **evaluation criteria,---**except as otherwise provided, the evaluation of proposals shall be carried out giving due consideration to quality and cost;

(e) **type of contract,---**the procuring entity, depending on the circumstances, may use one of the following types of contract, namely:

(i) lump sum contract will be used mainly for assignments in which the content, duration of the services and the required output are unambiguously defined;

(ii) time based contract will be used when it is difficult to define the scope and the length of services;

(iii) hourly or daily rates will be used for small projects, especially when the assignment is for less than a month; and

(iv) any other, based on combination of the above and including out of pocket expenses, where required;

(f) the consultant shall submit a bid security at the rate of 2 percent of the consulting cost which shall be forfeited in case he refuses to sign the contract agreement; and

(g) special provisions,--the procuring entity may specify any other requirement related to the assignment or contract etc, where required.

(3) The procuring entity will invite the prospective consultants to submit their technical and financial proposals in separately sealed envelopes. The procuring entity shall give deadline for submission of proposals. Consultants shall be given adequate time for preparing their proposals which shall not be less than four weeks.

28. Selection process of individual consultants.---(1) Individual consultants may not be required to submit proposals, and shall be selected based on their qualifications for the assignment.

(2) Individual consultants shall be selected by comparing the qualifications of at least three consultants among those who have expressed interest in the assignment or have been approached directly by the procuring agency. Individual consultants considered for the comparison of qualifications shall meet the minimum relevant qualifications, and the one selected to be employed by the procuring agency shall be the best qualified and shall be fully capable of carrying out the assignment.

(3) An individual consultant may be selected on a single-source basis (with due justification) in exceptional cases; such as the following--

(a) for a task that is a continuation of previous work that the consultant has carried out and for which the consultant was selected competitively;

(b) in an emergency situation resulting from a natural disaster; and

(c) when the individual is the only consultant qualified for the assignment.

(4) For key assignments, interviews may be set up, and invited candidates should be paid travel and subsistence, as needed. Capability of the candidates should be evaluated.

29. Professional liability of consultants.--(1) The consultant selected and awarded a contract shall be liable for consequence of errors or omissions on its part. The extent of liability of the consultant should be incorporated in the contract and in no case should it be less than remunerations excluding the out of pocket expenses, nor should the liability exceed twice the remunerations.

(2) The procuring entity may demand insurance on part of the consultant to cover its liability as stated above, and necessary costs shall be borne by the consultant which shall be reimbursed by the procuring entity as out of pocket expenses by the consultant.

(3) The consultant shall be held liable for all losses or damages and short comings in deliverance etc, suffered by the procuring entity as a result of mis-conduct or inadequate services in performing the consulting services.

CHAPTER

MISCELLANEOUS PROVISIONS

30. Procurement planning.---Each procuring entity shall plan its procurements with due consideration to transparency, economy, efficiency and timeliness, and shall ensure equal opportunities to all prospective bidders in accordance with section 22 of the Act.

31. Limitation on splitting or regrouping of proposed procurement.--A procuring entity shall announce in an appropriate manner, all proposed annual procurements and shall proceed accordingly without any splitting or regrouping of the procurements so planned.

32. Procurement committees.-- (1) Each procuring entity shall constitute committees, in accordance with delegation of financial powers, separately for procurement of goods, works and services.

(2) The committees shall have a representative each from the accounts or finance or planning sections of the procuring entity apart from others.

(3) A technical member shall be inducted from the relevant line department of Government or hired in all procurements of works or in exceptional cases, provided that procurement is technical and complex in nature.

33. Bid solicitation documents.--(1) A procuring entity shall apply bid solicitation documents as are applicable and are found consistent with the provisions of the Act and rule 34 of these rules, till such time when standard bidding documents are developed and prescribed in accordance with provisions of the Act and the rules.

(2) In case of procurement of works, solicitation documents shall contain technical specifications, drawings and designs, bill of quantities and estimated costs whatever applicable, evaluation criteria, expected commencement of contract and time period for completion, bid validity,

securities demanded, payment schedule, general and special conditions of contract, in case of procurement of works.

(3) In case of procurement of goods and services, including consulting services, the standard bidding document shall include scope of work and terms of reference, the evaluation criteria, the extent of bid validity, quantity, quality and specifications; qualification and experience of consultants, securities, approach and methodology, work plan and delivery schedule, pre-shipment inspection where applicable, schedule of payments and general and special conditions of the contract.

(4) Apart from the above, any other document or information or detail that the procuring entity may deem necessary, shall be included in the solicitation documents, unambiguously.

(5) Solicitation documents shall be made available to the bidders from the date of their issuance to the closing date on submission of required fee by the prospective bidder whether in person or, if so requested through an authorized request in writing. In case the request is made through courier, it shall accompany a bank draft in favor of the procuring entity including the cost of return delivery.

(6) In case where the procuring entity deem necessary may, keep a time period ending earlier than the closing date of tender or bid, for obtaining bid solicitation documents, provided that it is not less than the minimum response time provided in rule 34.

(7) In case of modification of solicitation documents by the procuring entity in accordance with section 23(9) of the Act, it shall do so by issuing an addendum or corrigendum and intimate the bidders publicly or individually, in case it has issued the solicitation documents, 5 days before the closing date. In case, the changes are substantial, the time for submission may be extended proportionately, by issuing timely intimation to all bidders.

34. Response time.---(1) The procuring entity may decide the response time for receipt of bids or proposals including proposals for pre-qualification from the date of publication of an advertisement or notice, keeping in view the contract's complexity, and urgency. However, under no circumstances the response time shall be less than fifteen days for national competitive bidding and thirty days for international competitive bidding from the date of publication of advertisement or notice in the national newspaper.

(2) The response time shall be calculated from the date of first publication of the advertisement in a newspaper or posting on the web site, as the case may be.

(3) In situations where publication of such advertisements or notices has occurred in both electronic and print media, the response time shall be calculated from the day of its first publication in the newspapers.

35. Bid validity.--(1) Bidders shall be required to submit bids valid for a period specified in the bid documents which shall be sufficient to enable a procuring entity to complete the evaluation and comparison of bids and obtain all necessary approval so that a contract can be awarded within that period.

(2) A procuring entity shall complete evaluation of bids and award of contract within the initial period of bid validity. An extension of bid validity, if justified by exceptional circumstances, shall be required in writing from all bidders before the expiry date. Bidders consenting to extend their bid validity period shall also correspondingly extend the validity of their bid security.

(3) A bidder not agreeing to extend its bid validity period may do so without having his bid security, forfeited and in this case its bid will no longer be considered in the evaluation proceedings.

(4) The bid security shall be forfeited if a bidder withdraws his bid, with in the validity period thereof or, in the case of a successful bidder, who repudiates the contract or fails to furnish performance security.

36. Pre-qualification process.--(1) The procuring entity engaging in pre-qualification shall announce, in the pre-qualification documents, all information required for pre-qualification including instructions for preparation and submission of the pre-qualification documents, evaluation criteria, list of documentary evidence required of contractors or consultants to demonstrate their respective qualifications and any other information that the procuring entity deems necessary for pre-qualification.

(2) The procuring entity shall provide a set of pre-qualification documents to any contractor or consultant, on request and subject to payment of document fee if applicable, which shall not exceed cost of printing and providing the documents.

(3) The procuring entity shall promptly notify each contractor or consultant submitting an application to pre-qualify whether or not it has been pre-qualified and shall make available to any person directly involved in the pre-qualification process, upon request, the names of all contractors or consultants who have been pre-qualified. Only contractors or consultants who have been pre-qualified shall be entitled to participate.

(4) The procuring entity shall communicate on request, to those contractors or consultants who have not been pre-qualified the reasons for not pre-qualifying them.

37. Submission of bids and bid opening.--(1) Bids shall be invited through a procuring officer of the procurement entity.

(2) A procuring entity shall require bidders to submit sealed written bids or in such other manner as may be prescribed in the solicitation documents.

(3) The procuring entity shall issue the bidder with a receipt showing the date and time when the bid was received.

(4) No bids or tenders received after the prescribed time and date in the solicitation documents or in accordance with subsequent corrigendum, shall be entertained.

(5) The method for submission of bids shall be determined by the type, complexity and evaluation method of the procurement in accordance with these rules.

(6) All announcements pertaining to public procurement shall specify the last date for submission of bids as well as the public bid opening which shall be the same.

(7) The bids, technical or financial as the case may be, shall be opened at the prescribed time provided in the solicitation documents in the presence of the procurement committee and the bidders who choose to be present.

(8) The name of the bidder, bid modifications, discounts or withdrawals, presence of bid security or affidavit as the case may be and the total amount of each bid and any alternatives, if so permitted, shall be read out aloud and recorded, and a copy of the record shall be made available to any bidder on request.

(9) No bidder shall be allowed to withdraw his bid till award of the contract or till bid is valid, whichever is earlier.

(10) A procuring entity may ask bidder for clarification of the bid to assist in the evaluation. To avoid delays, the procuring entity may hold a pre-bid conference with the prospective bidders at least five working days before the last day for submission of bids if the procurement is of complex nature and high value.

38. Confidentiality.--The procuring entity shall keep all information regarding the bid evaluation confidential until the time of the announcement of the evaluation report in accordance with the requirements of rule 45 of these rules.

39. Bid evaluation.— (1) All bids shall be evaluated in accordance with the evaluation criteria and other terms and conditions set forth in the bidding documents.

(2) For the purpose of comparison of bids quoted in different currencies, price shall be converted into a single currency specified in the bidding documents. The rate of exchange shall be the selling rate prevailing seven working days before the date of opening of the bids specified in the bidding documents**,** as notified by the state bank of Pakistan.

(3) A bid once opened in accordance with the prescribed procedure shall be subject to only those rules, regulations and policies that are in force at the time of issuance of notice for invitation of bids.

40. Discriminatory and difficult conditions.---Save as otherwise provided, no procuring entity shall introduce any condition, which discriminates between bidders or that is considered to be met with difficulty. In ascertaining the discriminatory or difficult nature of any condition reference shall be made to the ordinary practices of that trade, manufacturing, construction business or service to which that particular procurement is related.

41. Open tendering with international competition.--- When, in the absence of domestic capacity, effective competition cannot be obtained unless special efforts are made to attract international competition, international competition may be solicited in accordance with the provisions of the Act complemented with the following provisions:

(a) the tender documents shall be in English language;

(b) the invitation to tender shall be in English language and shall be placed in a newspaper of sufficient circulation to attract foreign competition and may also be placed on international web pages famous for international bidding advertisement. In addition, a procuring entity may transmit such invitations to their embassies and trade representatives of potential supplier countries;

(c) the time allowed for submission of tenders shall be sufficient for the invitation to reach bids, depending on the complexity and nature of procurement and for enabling them to prepare and submit bids but in no case less than thirty days;

(d) technical specifications shall, to the extent compatible with national requirements, be based on international standards or standards widely used in international trade;

(e) bidders shall be permitted to express their bids, as well as any bid and performance security documents to be presented by them in their respective home currencies or in a currency widely used in international trade and stated in the solicitation documents;

(f) general and special conditions of contract shall be of a kind generally used in international

trade; and

(g) standard bidding documents (SBDs) for goods, works and services shall be used for international competitive bidding (ICB) as well.

42. Post bid negotiation.---Procuring entity may negotiate with the highest ranked bidder regarding methodology, work plan, staffing and special conditions of the contract. In case of consulting services the procuring agency shall not permit substitution of key staff, unless both parties agree that undue delay in selection process makes such substitution unavoidable. Similarly, negotiations shall not seek changes in the rates quoted by the bidder. In case of failure of negotiations, the procuring agency may invite the second ranked bidder as per the evaluation report.

43. Disqualification of suppliers, contractors and consultants.---The procuring entity shall disqualify a supplier or contractor or consultant if it finds, at any time, that the information submitted by him concerning his qualification as supplier or contractor was false and materially inaccurate or incomplete. However, the bidder may have right to appeal against the decision in accordance with section 35 of the Act and grievances redressal mechanism framed under the Act.

44. Blacklisting of suppliers, contractors and consultants.---(1) The procuring entity shall specify a mechanism and manner to permanently or temporarily bar, from participating in their respective procurement proceedings, suppliers contractors and consultants who either consistently fail to provide satisfactory performances or are found to be indulging in corrupt or fraudulent practices or abandon the work prematurely resulting in loss to Government . Such barring action shall be duly publicized and communicated to the Authority, provided that any contractor or consultant who is to be blacklisted shall be accorded adequate opportunity of being heard in person.

(2) The bidder will have a right to complain to the administrative Secretary of the procuring entity or to file an appeal to the Authority in accordance with section 35 of the Act and regulations or guidelines to be framed under it.

45. Announcement of evaluation reports.---Procuring entities shall announce the results of technical bid evaluation in the form of a report before opening of the financial bids, to all bidders. The procuring entity shall also announce the final results of a bid evaluation giving justification for acceptance or rejection of bids at least ten days prior to the award of a contract and place the same on its and Authority website.

46. Approval of contract award.--(1) The procurement committee shall submit the bid evaluation report with its recommendations for award of contract, to the approving authority in accordance with the delegation of powers under the financial rules and the power of re-appropriation rules 2001, in an expeditious manner, so that the award can be notified before expiry of the bid validity period, without having to seek extension, in conformity with the provisions of section 31 of the Act and these rules.

(2) All contract awards shall be made public through publication on Authority website.

47. Rejection of bids.---(1) The procuring entity may reject all bids or proposals at any time prior to the acceptance of a bid or proposal. The procuring entity shall upon request communicate to any contractor or consultant who submitted a bid or proposal, the grounds for rejection of all bids or proposals.

(2) The procuring entity shall incur no liability, solely by virtue of its invoking sub-rule (1) towards contractors or consultants who have submitted bids or proposals.

(3) Notice of the rejection of all bids or proposals shall be given promptly to all contractors or consultants that submitted bids or proposals.

48. Re-bidding.---(1) If the procuring entity has rejected all bids under rule 47 it may call for a re-bidding.

(2) The procuring entity before invitation for re-bidding shall assess the reasons for rejection and may revise specifications, evaluation criteria or any other condition for bidders as it may deem necessary.

49. Payments.---All procuring agencies shall make prompt payments to contractors and consultants against their invoices or running bills within the time given in the conditions of the contract.

50. Entry into force of the procurement contract.--- A procurement contract shall come into force-

(a) where no formal signing of a contract is required, from the date the notice of the acceptance of the bid or purchase order has been given to the bidder whose bid has been accepted. Such notice of acceptance or purchase order shall be issued within 15 days thereof; or

(b) where the procuring entity requires signing of a written contract, from the date on which the signatures of both the procuring entity and the successful bidder are affixed to the written contract. Such affixing of signatures shall take place within 15 days after the letter of acceptance or award has been issued:

Provided that where the coming into force of a contract is contingent upon fulfillment of a certain condition or conditions, the contract shall take effect from the date whereon such fulfillment takes place.

51. Closing of contract.--(1) Except for defect liability or maintenance by the contractor or consultant, as specified in the conditions of contract, performance of the contract shall be deemed close on the issue of over all delivery certificate or taking over certificate which shall be issued within thirty days of final taking over of goods, or receiving the deliverables or completion of works enabling the contractor or consultant to submit final bill.

(2) In case of defect liability or maintenance period, defect liability certificate shall be issued within thirty days of the expiry of the said period enabling the contractor or consultant to submit the final bill. Except for unsettled claims, the bill shall be paid within the time given in the conditions of contract, which shall not exceed sixty days to close the contract.

(3) Relevant provision for closing of contract shall be a part of the bid solicitation document.

52. Record of procurement proceedings.--(1) All procuring entities shall maintain a record of their respective procurement proceedings along with all associated documentation.

(2) Such maintenance of record shall be subject to the regulations framed in this regard from time to time.

53. Public access and transparency.--As soon as a contract has been awarded, the procuring entity shall make all documents related to the evaluation of the bid and award of public contract:

Provided that where the disclosure of any information related to the award of a contract is of proprietary nature or where the procuring entity is convinced that such disclosure shall be

against the public interest, it can withhold only such information from public disclosure subject to the prior approval of the administrative department.

54. Mis-procurement.--Any breach of these rules shall account to mis-procurement and the person responsible for such breach shall be liable to be proceeded under the relevant law.

55. Repeal.-- The Khyber Pakhtunkhwa Procurement of Goods, Works and Services Rules, 2003 is hereby repealed**.**

SECRETARY TO
GOVERNMENT OF KHYBER PAKHTUNKHWA
FINANCE DEPARTMENT

Appendix 2:
Khyber Pakhtunkhwa Public Procurement Regulatory Authority Act 2012

PROVINCIAL ASSEMBLY SECRETARIAT

KHYBER PAKHTUNKHWA

NOTIFICATIION

Dated Peshawar the 20th September 2012

NO. PA/Khyber Pakhtunkhwa/Bills/2012/6059--- The Khyber Pakhtunkhwa Public Procurement Regulatory Authority Bill 2012, having been passed by the Provincial Assembly of Khyber Pakhtunkhwa on 3rd September 2012 and assented to by the Governor of the Khyber Pakhtunkhwa on 16th September 2012 is hereby published as an Act of the Provincial Legislature of the Khyber Pakhtunkhwa.

THE KHYBER PAKHTUNKHWA PUBLIC PROCUREMENT REGULATORY AUTHORITY ACT 2012

(KHYBER PAKHTUNKHWA ACT NO XI OF 2012)

(First published after having received the assent of the Governor of the Khyber Pakhtunkhwa in the Gazette of the Khyber Pakhtunkhwa (Extraordinary), dated the 20th September, 2012)

AN

ACT

to provide for the legal and regulatory framework for public procurement.

WHEREAS it is expedient to provide for the legal and regulatory framework for public procurement, and other matters connected therewith or incidental thereto, for the purposes hereinafter appearing;

It is hereby enacted as follows:

1 Short title, extent and commencement.---

(1) This Act may be called the Khyber Pakhtunkhwa Public Procurement Regulatory Authority Act, 2012.

(2) It extends to the whole of the Khyber Pakhtunkhwa.

(3) It shall come into force at once.

2 Definitions.---

(1) In this Act, unless there is anything repugnant in the subject or context,-

(a) "Authority" means the Khyber Pakhtunkhwa Public Procurement Regulatory Authority established under section 4;

(b) "bidder" means a contractor, supplier, vendor or consultant who offers his services for procurement of goods works, or services in response to bid solicitation by a procuring entity;

(c) "best evaluated bid" means,-

i. in case for procurement of goods and services, the highest ranking fair bid in accordance with the evaluation criteria set forth in the bid solicitation documents;

ii. in case of procurement of works, the lowest responsive evaluated bid will be the 'best evaluated bid';

(d) "bidding" means the formal procurement procedure under which sealed bids are invited, received, examined and evaluated for the purpose of awarding a contract;

(e) "bidding documents" means the data, information and representations submitted by the bidder on the bid solicitation documents advertised and made available by the procuring entity;

(f) "bid solicitation documents" means the documents prepared by the procuring entity on the format of standard bidding documents for solicitation of bids;

(g) "Board" means the Board of Directors of the Authority;

(h) "Chairperson" means the Chairperson of the Board;

(i) "consultant" means a person, a firm, a company or an organization undertaking supply of services;

(j) "contract' means a contract as defined in the Contract Act,1872;

(k) "goods" means articles and objects of every kind and description including raw materials, intermediate inputs, finished goods, products, equipments, computers, machinery, spare-parts and commodities in solid, liquid or gaseous form, electrical, mechanical as well as incidental services such as installation, transport or vehicles, maintenance and similar obligations related to the supply of goods, if the value of these services does not exceed the value of such goods;

(l) "Government" means the Government of the Khyber Pakhtunkhwa;

(m) "Managing Director" means the Managing Director of the Authority;

(n) "mis-procurement" means public procurement in contravention of any of the provision of this Act or any other law in respect of or relating to public procurement, including any rules, regulations, orders or instructions made in this behalf and for the time being in force;

(o) "prescribed" means prescribed by rules made under this Act;

(p) "procurement object" means goods, works or services to be procured by a procuring entity through public procurement process;

(q) "procuring entity" means-

i. a Department or any Office of Government including a project unit; or

ii. any Board, Commission, Council or other bodies established by or under a provincial law; or

iii. semi-autonomous or autonomous bodies which are owned or controlled by Government;

(r) "province" means the Khyber Pakhtunkhwa;

(s) "public procurement" means acquisition, temporary or permanent or on lease, of goods or services, or undertaking of works by contractual means, financed wholly or partly out of Fund by any procuring entity;

(t) "responsive" means conformity of a bid/technical proposal submitted by the prospective bidders to the statement of requirements in terms of section 24 of this Act;

(u) "rules" means the rules made under this Act;

(v) "services" means any object of procurement which does not constitute procurement of works or goods and includes consulting services;

(w) "standard bidding documents" means the format/forms approved and notified by the Authority for submission of proposals and bids by the bidders in a public procurement process; and

(x) "works" means any constructional work consisting of erection, assembly, repair, renovation or demolition of a building or structure or part thereof, such as site preparation, excavation, installation of equipment or materials and decoration, finishing and includes allied services such as mapping, satellite photography, seismic investigations and similar activities, if the value of the services does not exceed that of the works themselves.

(2) Words, expressions and terms not specifically defined in this Act and the rules shall have the same meanings as attributed to them in the relevant trade and industry practices.

3 **General principles of public procurement.---**All public procurement shall be conducted in such a manner as provided in this Act, rules and regulations made under this Act and shall promote the principles of transparency, economy, value for money, accountability and swift grievance handling.

4 Establishment of the Authority.---

(1) Soon after the commencement of this Act, Government shall by notification in the official Gazette establish an Authority to be known as Khyber Pakhtunkhwa Public Procurement Regulatory Authority with its headquarters at Peshawar.

(2) The Authority shall as soon as possible establish its own secretariat and may set up its regional offices in such place or places in the Khyber Pakhtunkhwa, as it may deem appropriate.

(3) The Authority shall be a body corporate, having perpetual succession and a common seal, with power to acquire and hold property and to enter into contracts, and may by the said name sue and be sued, and shall exercise all powers necessary for the purposes under this Act.

5 **Powers and Functions of the Authority.---**The Authority shall perform functions and exercise powers as follows:

(a) hear and dispose of appeals against the orders of procuring entity;

(b) formulate standard bidding documents, separately for procurement of Goods, Works and services, for all procuring entities to emulate as the format for bid solicitation documents for submission of proposals and bids by the bidders in a public procurement process;

(c) shall assist the major procuring entities to engineer/re-engineer their business procedures and design their Procurement Manuals in compliance with this Act;

(d) ensure that all the procuring entities organize and maintain a system for the publication of or posting on departmental official website of data on Public Procurement opportunities, awards and any other relevant information;

(e) ensure that all procuring entities organize and manage database and web site which shall warehouse information and publications on public procurement;

(f) conduct performance review based on pre determined indicators and benchmarks through third party validation by State Bank of Pakistan certified category 'A' chartered accountant firm;

(g) organize and manage capacity-building of procurement personnel in all the procuring entities in the Province;

(h) conduct research and take measures to further principles of public procurement enunciated in this Act;

(i) recommend to the Government, measures necessary to improve the quality of public procurement in the Province;

(j) recommend to the Government, measures necessary to enhance transparency and ensure accountability in the public procurement process in the Province;

(k) advise Government on all matters pertaining to public procurement; and
(l) perform such other functions and exercise such powers as maybe necessary to further objectives of this Act and perform such other functions as assigned by the Government from time to time.

6 **Management.---**The general directions and administration of the Authority and its affairs shall vest in the Board, which shall exercise all powers and do all acts, which may be exercised or done by the Authority, in accordance with the provisions of this Act.

7 Board of Directors.---

(1) Government shall constitute a Board of Directors for the management and administration of the Authority consisting of,-
(a) (a) Secretary to the Government, Chairperson. Finance Department;
(b) (b) Secretary to the Government, Member. Planning & Development Department or his nominee not below the rank of an Additional Secretary;
(c) (c) Secretary to the Government, Member. Works and Services Department or his nominee not below the rank of an Additional Secretary;
(d) (d) Secretary to the Government, Member. Irrigation Department or his nominee not below the rank of an Additional Secretary;
(e) (e) Secretary to the Government of Public Member Health Engineering Department or his nominee not below the rank of an Additional Secretary;
(f) (f) Secretary to the Government, Member. Health Department or his nominee not below the rank of an Additional Secretary;
(g) (g) three persons from the private sector Members. i.e. from trade and industry, academia, civil society and professional associates;
(h) (h) Managing Director of the Authority; Member/Secretary.

(2) Government shall notify the terms and conditions for appointment of non-official members of the Board.
(3) The non-official members shall be appointed by Government for a period of three years.
(4) Six members shall constitute the quorum for convening meeting of the Board.
(5) The meeting of the Board shall be presided over by the Chairperson and in his absence by one of the ex-officio Members to be nominated by the Chairperson in this behalf.
(6) All decisions in the meeting shall be taken by majority of votes. Each member, including the Chairman, shall have one vote, but in the event of tie of votes, the Chairman shall have a second or casting vote.

8 Managing Director.---

(1) Government shall appoint the Managing Director of the Authority for a period of three years on such terms and conditions as it may determine and may extend his appointment for a second term:

Provided that the entire period of appointment shall not exceed six years.

(2) The Managing Director shall be a senior civil servant of BS-20 or a reputed professional with fifteen years post-qualification experience, preferably in public procurement. However, no such person shall be appointed as Managing Director who has been:
(a) convicted by a court of law; or
(b) removed from any service on a charge of misconduct.

(3) The Managing Director shall be the Chief Executive and the Principal Accounting Officer of the Authority.
(4) In the performance of his functions, the Managing Director shall work within the framework of the general policy and guidelines laid down by the Board.

9 Establishment of the Authority Fund.---

(1) There shall be a Fund to be known as Khyber Pakhtunkhwa Public Procurement Regulatory Authority Fund, hereinafter referred to as Authority Fund, which shall vest in the Authority and shall be utilized by the Authority to meet charges and expenses in connection with the affairs of the Authority under this Act including salaries and other remunerations of the non-official members and employees of the Board.

(2) The Authority Fund shall consist of all the money received by the Authority.

10 Custody and investment of the Authority Fund.---

(1) The Board may keep the Authority Fund in any Scheduled Bank, as may be approved by it.

(2) Nothing in sub-section (1) shall be deemed to preclude the Board from investing any such moneys which are not required for immediate expenditure in any of the securities described in section 20 of the Trust Act, 1882 (Act No. II of 1882), or placing them in fixed deposit with a Bank approved by the Board or in such other manner as may be approved by it.

11 **Maintenance of accounts.---**The Board shall maintain complete and accurate books of accounts of its actual expenses and receipts in such form as the Government, in consultation with the Local Audit Department determined.

12 **Audit.---** The Authority shall cause to carry out the audit of its accounts by Auditor General of Pakistan provided that provision shall be made for an internal audit of the finances of the Authority.

13 **Appointment of officers, advisors etc.---**The Authority may, from time to time and subject to resources, appoint such officers, servants, advisers, consultants, referees and experts as it may consider necessary for performance of its functions. The Authority shall notify the procedure for appointments and fixation of terms and conditions after approval of the Board of Directors.

14 Responsibility of procuring entity.---

(1) Each Procuring Entity shall be responsible for carrying out public procurement subject to the provisions of this Act, and the rules, the administrative instructions and the standard bidding documents made there-under:

Provided that-

i. Government on a specific request of the procuring entity or in public interest may exempt a procuring entity from some or all of the provisions of this Act for which reasons shall be recorded in writing. Government may seek comments of the Authority, if so required;

ii. for District Governments, the procuring entity may route a justifiable case for exemption to the Government by the District Coordination Officer, through Secretary Local Government Department;

iii. Government may exempt the procurement of an object or a class of objects, in national/public interest, from some or all provisions of this Act, for which reasons shall be recorded in writing; and

(2) Government shall notify the exemption and publish the same for public consumption in the printed media.

14A. Transparency, accountability and fairness.--- All procurement shall be conducted in a manner which promotes transparency, accountability and fairness.

14B. Competition.--- Except as otherwise provided for in this Act and the rules, all procurement shall be conducted so as to maximize competition and to achieve value for money:

Provided that the exception shall be made only for acquisition of services for reasons to be recorded in writing by the procuring entity.

15 Confidentiality.---

(1) A procuring entity shall not, except when required to doso by an order of a Court, disclose any information if the disclosure would:
   (a) cause a breach of this law or any other law; or
   (b) impede law enforcement; or
   (c) prejudice legitimate commercial interests of the parties; or
   (d) inhibit fair competition; or
   (e) not be in public interest.

(2) (2) A procuring entity shall not disclose any information relating to the contents of offers, pre-qualification submissions and actual content of bids, proposals or quotations other than in a summary form setting out the evaluation and comparison of tenders, proposals or quotations received before award of the contract. The format/forms for announcement of bids evaluation and determination of the best evaluated bid shall be prescribed.

16 Ethics.---

(1) All procurements shall be carried out in accordance with such Code of Ethics as may be prescribed.

(2) Public officials as well as experts, engaged to deliver specific services in public procurement proceedings including evaluation of bids, shall be required to sign a Code of Ethical Conduct as may be prescribed.

(3) All vendor of goods, works or services shall be required to sign a declaration of compliance with such Code of Conduct as may be prescribed.

17 International Obligations.---Notwithstanding anything contained in this Act, the international obligations of Government arising out of bilateral or multilateral Agreements including Treaties, financing agreements, or agreements by Government shall continue to remain and be valid, binding and operative.

18 Preference and reservation.---

(1) If an agreement in terms of section 17provides for preference to national vendors, the procuring entity shall ensure that such preference is unambiguously stated in the standard bidding documents and announcements for the procurement including advertisement and terms of reference and tender documents.

(2) Each procuring entity shall permit prospective bidders to participate in procurement proceedings without regard to nationality, except where a procuring entity decides to limit such participation to national providers or participation of any nationality is forbidden by any law or by any instruction/policy of the Federal Government or other Provincial Government.

(3) If participation is restricted on the basis of nationality, the procuring entity shall record in the procurement proceedings a statement of grounds and circumstances relied upon.

19 Public Accessibility.--- This Act, the rules made there-under, guidelines, forms, bidding documents and/or decisions of Government or procuring entity relating to procurement shall be placed on a web-site of the Authority in addition to the website of the procuring entity or the Government, as the case may be, and which will also provide copies of these documents to the public at a fee not exceeding the cost of printing/reproduction of the documents.

20 Records.---

(1) The procuring entity shall:
   (a) maintain detailed records of all procurement proceedings in the manner as prescribed; and
   (b) preserve, maintain and safeguard all relevant documents issued and received as shall be set out in the rules.

(2) The records of the procurement process of the procuring entity shall be open to internal and external audit or to procurement post-review in the prescribed manner or for scrutiny or inspection by Government or in accordance with any law.

21 Communication.---

(1) All communications between a procuring entity and the bidder or vendor of procurement object shall be in writing.

(2) Forms of communication as well as the name of the focal person shall be specified in solicitation documents.

22 Procurement planning.---

(1) Each procuring entity shall plan its procurements with due consideration to transparency, economy, efficiency and timelines, and shall ensure equal opportunities to all prospective bidders.

(2) All procurement requirements must be documented and approved by the procuring entity prior to commencement of procurement proceedings.

(3) In specified circumstances, a procuring entity may proceed with the procurement proceedings except for award of contract when the availability of funding in the full amount over the required period remains to be confirmed/approved by the competent authority:

Provided that the project has been approved or has received anticipatory approval from the competent authority/forum or is otherwise within the competence of the procuring entity and budget provision exists.

23 Bid Solicitation documents.---

(1) A procuring entity shall adopt standard bidding documents designed under this Act and insert/add specifications into the standard bidding documents for each procurement.

(2) Bid solicitation documents shall specify in detail the terms and conditions, including a statement of general conditions of contract, which shall apply to the resultant contract.

(3) The general conditions of contract shall not be modified.

(4) Each procuring entity shall solicit bids based on performance or functional specifications and not on restrictive or proprietary specifications of a particular brand.

(5) A procuring entity may introduce special conditions of contract to elaborate and qualify the general conditions of contract, where applicable, furnishing detailed justification and reasons thereof, in the bid solicitation documents.

(6) Bid solicitation documents shall invariably include an unambiguous statement giving an accurate and complete description of the procurement objects to pursue the principles of public procurement enunciated in section 3 of this Act.

(7) Statement of requirements shall be in the form of technical specifications, terms of reference, scope of work, briefs or its equivalent as appropriate.

(8) Bid solicitation documents shall be made available to the bidders from the date of their issuance to the closing date on submission of required fee by the prospective bidder whether in person or, if so requested, through mail.

(9) At any time prior to the deadline for submission of bids, the procuring entity may, on its own initiative or in response to a request for clarification by a bidder, modify the bid solicitation documents by issuing an addendum or corrigendum.

(10) If the procuring entity considers necessary, it may extend the closing date, after recording reasons in writing, to enable bidders to take the addendum or corrigendum, as the case may be, fully into account in preparing their bids.

(11) No change in the substance of bids, including changes in price, shall be sought, offered or permitted after the date and time of bid closing, except as otherwise provided for in the rules.

24 Submission of bids.---

(1) A procuring entity shall require the bidders to submit sealed written bids or in such other manner, as may be prescribed.

(2) The method for submission of bids shall be determined by the type, complexity and evaluation method of the procurement in accordance with the rules.

(3) All announcements pertaining to public procurement shall specify the last date for submission of bids as well as the public bid opening which shall be the same.

(4) The bidding period shall be reasonable to allow bidders to prepare and submit their bids and shall not be reduced.

(5) A bidder may withdraw his bid at any time before the deadline for submission of bids, unless otherwise specified.

(6) To avoid delays, the procuring entity may hold a pre-bid conference with the prospective bidders if the procurement is of complex nature and high value.

25 Minimum qualification of bidders.---A procuring entity shall require all bidders to meet minimum qualification criteria to participate in public procurement to affirm/ensure that the bidder,-

(a) has the legal capacity to enter into the contract;

(b) has the prescribed technical proficiency, equipments/plant and/or relevant certified experience;

(c) is neither insolvent nor bankrupt;

(d) is not in the process of winding up nor his/her properties are under the control of receiver nor his/her business activities have been suspended nor legal proceedings for any of the foregoing are imminent or have been initiated against him/her; and

(e) has fulfilled all obligations under law for the time being in force.

26 Enlistment and Pre-Registration.---For the enlistment and pre-registration, the following conditions should be adopted, namely:

(a) enlistment and pre-registration shall be carried in a manner as may be prescribed;

(b) provincial enlistment and pre-registration shall be undertaken by a committee which shall be chaired, steered, represented and coordinated by Works and Services Department, with representation from Irrigation Department and Local Government, Elections and Rural Development Department.

27 Best practices and industry standards.---Procuring entities shall at all times use industry standards defined and codified by internationally recognized trade associations and professional bodies in the appropriate fields in international bidding where available and local bidding where laid down.

28 Procurement process and evaluation.---For the procurement process and evaluation,-

(a) the procurement system would allow a single stage single envelope, a single stage, two envelopes, a two stage single envelope and two stage two envelopes procedures depending on the nature of the procurement or as laid down in procurement rules made under this Act;

(b) the rules shall prescribe the threshold and method for single source single quotation, request for quotations and open competitive procurement;

(c) the methodology of evaluation shall be determined by the type, value and complexity of the procurement as may be prescribed by the Authority;

(d) all bid solicitation documents shall fully and comprehensively detail the evaluation methodology and criteria relevant to the particular procurement;

(e) contract shall be awarded to the bidder whose bid is responsive and is determined as the best evaluated bid ascertained on the basis of methodology and criteria mentioned in clause (d)above and in the definition; and

(f) no evaluation criteria other than those stipulated in the solicitation documents shall be taken into account.

29 Disqualification and debarment of bidders.---

(1) The procuring entity shall disqualify a bidder if it finds at any time that the information submitted concerning qualifications of the bidder was false, or materially inaccurate or incomplete.

(2) A procuring entity may debar a bidder from taking any further part in a procurement proceeding or in future procurement proceedings if the bidder-

(a) forms part of a cartel/ring with a view to discourage fair competition in the bidding process; or

(b) has failed to complete his earlier contract, within a period of three years of the initiation of procurement proceeding, on ground that his approved bid was or has become unprofitable or would result in his suffering of loss; or

(c) offers or attempts to offer inducement of any sort; such baring actions will be duly publicized and communicated to the Authority.

30 Rejection of bids.---A Procuring Entity may reject any or all bids communicating the reasons for rejection in writing to the Authority at any time prior to the award of a contract.

31 Award of Contract.---The procuring entity shall award contract on the following conditions, namely:

(a) the contract shall be awarded on the basis of the best evaluated bid;

(b) the best evaluated bid shall be determined on the basis of total conformity to the evaluation criteria which may include quality or cost or both;

(c) the procedure to determine the best evaluated bid under different methods of procurement and consequent award of contract shall be prescribed by the rules made under this Act;

(d) the award of contract shall be made as per timeframe prescribed in the rules made under this Act;

(e) a procuring entity shall complete evaluation of bids and award of contract within the initial period of bid validity to avoid the necessity of extensions;

(f) an extension of bid validity, where inevitable, shall be requested only in exceptional circumstances as may be prescribed and shall always be sought in writing from all bidders before the expiration date; and

(g) all contracts shall be confirmed through a written agreement signed by the successful bidder and the procuring entity, except as otherwise provided for in the rules.

32 Changes in bidders circumstances.---Any changes in the circumstances of the bidder during the procurement proceedings that could materially affect the capacity to execute the contract shall be immediately brought to the attention of the procuring entity by the bidder, other bidders or any other stakeholder.

33 Methods of procurement.---

(1) The procuring entities shall resort to open competitive bidding as the preferred method of procurement.

(2) The selection of the procurement procedure shall be made in accordance with the rules, and shall be approved by the concerned procuring entity prior to commencement of any procurement proceedings:

Provided that the procuring entities may exceptionally use other methods, including negotiations, in the following eventualities in accordance with the rules to cater for:

(a) procurements of small value through petty purchase or through request for quotations; and
(b) procurements through direct contracting in an emergency caused by nature or governments, for urgent requirements caused by unforeseeable events, single repeat order not exceeding fifteen percent of the original procurement, for considerations of intellectual property, if price is fixed by a Government in the country or procurement from another procuring entity/public sector organization within Pakistan.

34 Procurement Committees.---Procuring entities may constitute procuring Committees for procurement of goods, works and services.

35 Grievance Redressal Mechanism.---

(1) Any bidder aggrieved by any act of the procuring entity may follow the two tier grievance redressal mechanism in the following manner:
   a. file a complaint in writing to the head of procuring entity in accordance with prescribed procedure; and
   b. file an appeal to the Authority against the decision of the procuring entity within fifteen days in accordance with the prescribed procedure.

(2) The decision of the Authority on appeal shall be final.

36 Power to make rules.---Government may make rules for carrying out the purposes of this Act.

37 Repeal.---

(1) The Khyber Pakhtunkhwa Public Procurement of Goods, Works, Services and Consulting Services Ordinance, 2002 (Khyber Pakhtunkhwa Ord. No. XVIII of 2002) is hereby repealed.

(2) Notwithstanding the repeal of Khyber Pakhtunkhwa Procurement of Goods, Works, Services and Consulting services Ordinance, 2002 (Ord. No. XVIII of2002), any public procurement initiated under the repealed law, shall, if not inconsistent with the provisions of this Act shall be executed and dealt with in accordance with the provisions of repealed law.

38 Removal of Difficulties.---If any difficulty arises in giving effect to any of the provisions of this Act, Government may, by notification in the official Gazette, make such provision as may appear to it necessary for the purpose of removing the difficulty.

BY ORDER OF MR. SPEAKER
PROVINCIAL ASSEMBLY OF KHYBER
PAKHTUNKHWA

(AMANULLAH)
Secretary
Provincial Assembly of Khyber Pakhtunkhwa

Appendix 3: The Drugs (Labeling and Packing) Rules, 1986

1. Short title and commencement:

   (1) These rules may be called the Drugs (Labeling and Packing) Rules, 1986.
   (2) They shall come into force on the expiration of the period of one year beginning with their publication in the official Gazette.

2. Definitions: In these rules, unless there is anything repugnant in the subject, or context;

   (a) "international non-proprietary name" means the name of a drug as recommended by the World Health Organization or such other name as may be notified by theFederal Government in the Official Gazette;
   (b) "pharmacopoeia" means a publication mentioned in sub-clause (ii) of clause (z) of Section 3 of the Drugs Act, 1976 (XXXI of 1976);
   (c) "pharmacopoeial name" means the name of a drug as mentioned in the pharmacopoeia;
   (d) "Schedule" means a schedule to these rules; and
   (e) "registered medical practitioner" means a medical practitioner registered or provisionally registered under the Medical and Dental Council Ordinance, 1962(XXXII of 1962).

3. Manner of labeling: The following particulars shall appear either in print or in writing in inedible ink in a conspicuous manner on the label of the innermost container of a drug and also on the covering in which such container is packed, namely:

   (a) the registered name of the drug;
   (b) if the registered name is a proprietary name, then immediately following the registered name, the generic name or other name, if any, approved by the Registration Board, for this purpose small be printed within brackets with at least equal prominence as that of the brand name;
   (c) the international non-proprietary name or the pharmacopoeial name or the generic name, and if no such name is known, the chemical name, of each active ingredient of a drug with weight or measure in metric system, or the number of units of activity, as the case may be, expressed:
      i. in the case of oral liquid preparations, in terms of contents per specified volume, the volume being indicated in milliliters;
      ii. in the case of liquid parenteral preparations ready for administration, in terms of milliliters or percentage by volume or dose:

      Provided that in the case of a preparation contained in ampoule, it shall be sufficient if the ingredients are shown on the label or wrapper affixed to any package in which such ampoule is issued for sale:

      iii. in the case of drugs in solid form intended for parenteral administration, in terms of weight or unitage, per milligram or gram or per container;
      iv. in the case of tablets, capsules, pills and the like, in terms of the contents pertablets, capsule, pill or other unit, as the case may be; and
      v. in the case of other preparations, in terms of percentage by weigh or volume or unitage, per gram or milliliter, as the case may be;

(d) the name and principle place of business of the manufacturer;
(e) the drug manufacturing license number;
(f) the drug registration number;
(g) the date of expiry;
(h) Urdu version of the following:
    i. registered name of drug;
    ii. dosage (numerals in English shall be sufficient); and
    iii. instructions.
(i) the distinctive batch number, date of manufacture and the maximum retail price:

Provided that in the case of a drug packed in a strip of paper, or blister or foil, or contained in an ampoule of a capacity of not more than two milliliters or in an ampoule containing a sterile suture or ligature, and such strip, foil, blister or ampoule is placed in another package, and also in the case of printed collapsible tubes, it shall be sufficient to give the information on the outer packing containing such strip, foil, blister or ampoule:

Provided further that the Registration Board may allow relaxation of any of these conditions.

4. Labeling of drugs for internal use: The label of container of a drug meant for internal use, except a drug contained in a strip or foil or blister or collapsible tube, shall, in addition to the particulars required to be given under rule 3, bear in a conspicuous manner:

    i. if it contains a substance specified in the Schedule, the words "To be sold on prescriptions of a registered medical practitioner only"; and
    ii. if it contains not less than three per cent by volume an alcohol, a statement giving the quantity of alcohol in terms of average percentage by volume of absolute alcohol in the finished product.

5. Labeling of drugs for external use only: The label of a container of ointment, cream, liniment, lotion, liquid, antiseptic or any other drug for external application shall, in addition to the particulars required to be given under rule 3, bear in a conspicuous manner:

    i. the words "For external use only"; and
    ii. if the drug contains a substance specified in the Schedule, the words "Poison: for external use only".

6. Labeling of physician's samples: The label of a container of every drug intended for distribution to the medical profession as free sample shall, in addition to the particulars required to be given under these rules, bear the words "Physician's sample: Not for sale" which shall be overprinted or stamped:

    Provided that if the drug is packed in a strip of paper or blister or foil or contained in an ampoule of a capacity of not more than three milliliters or in a collapsible tube, it shall be sufficient to label the outer packing only with the said words.

7. Labeling of drugs for Government supply: The label of a container of every drug intended for the supply to any Government agency, including an autonomous body or a semi-Government Agency shall, while complying with the other labeling requirements of these rules, bear the words or mark reading "Government Supply" or such other words or mark as may be required by the agency concerned.

8. Labeling of drugs for veterinary use: The label of a container of drug for veterinary use shall bear in a conspicuous manner, preferably in red ink the words for veterinary use only.

9. Outer transparent wrapper not to require labeling: Nothing in these rules shall be deemed to require the labeling of any transport cover, wrapper, case or other covering used solely for the purpose of packing, transport or delivery of a drug.

10. Labeling of non-sterile surgical ligature and suture: Every container of, and every wrapper enclosing a surgical ligature or suture, other than a ligature or suture certified to be sterile and fit for surgical use without further sterilization, shall bear a label on which shall be printed or written in a conspicuous manner in indelible red ink the word

    "Non-sterile surgical ligature/suture: Not to be used for operation upon human body unless properly sterilized".

11. Use of letter to indicate specifications: If a drug is included in the recent edition of any publication specified in the rules, the name of relevant publication in conventional abbreviations (B.P., U.S.P., etc.) shall be printed in indelible ink, on the label to indicate that the drug conforms to the specifications set out in that publication.

12. Packing of finished drugs: Each finished drug ready of use-shall be packed in containers intended for retail sale to a hospital, dispensary, clinic or any other such institution.

13. Labeling of drugs manufactured for export or experimental purposes:

    (1) Nothing contained in rules 3 to 12 shall apply to a drug manufactured for experimental purposes which shall be labeled in accordance with rule 23 of the Drugs (Licensing, Registering and Advertising) Rules. 1976.

    (2) Labeling of drugs manufactured for export shall, in addition to meeting specific requirements of the importers, bear following particulars printed in indelible ink, on the inner most container and other packings of such drugs,

        i. name of drugs;
        ii. name and address of manufacturer; and
        iii. batch number and dates of manufacture and expiry date of the drug:

    Provided that in case of a drug packed in a strip of paper, foil or blister or contained in an ampoule of a capacity of not more than two milliliters or in a printed collapsible tube or in an ampoule containing a sterile suture or ligature and that such strip, foil, blister or ampoule is placed in another package, then it shall be sufficient to give name, date of expiry and batch number of the drug, name and address of the manufacturer on the inner-most container or its label, while full particulars shall be given on outer packing containing such strip, foil, blister, ampoule or tube.

14. Exemption: These rules shall not be applicable in respect of a drug made up ready for treatment, whether after or without dilution and is supplied by a person licensed to sell drugs on the prescription of a registered medical practitioner:

    Provided that the label bears the following particulars, namely:

    i. the name and address of the suppliers of the drug;
    ii. the name of the patient;
    iii. the number representing the serial number of the entries in the prescription register;
    iv. if the drug is for internal use, the dosage;
    v. if the drug is for external use, and does not contain a substance specified in the Schedule' the words "For external use only"; and

vi. if the drug is for external use and contains a substance specified in the Schedule, the words "Poison: for external use only".

THE SCHEDULE

To be sold by a retailer on the prescription of registered medical practitioner

1. C.N.S. stimulants.
2. Drugs affecting uterine motility.
3. Drugs inhibiting hormonal production.
4. Hormones and other steroidal preparation excluding preparations for external and topical use.
5. Narcotic drugs as per Single Convention on Narcotic Drugs, 1961.
6. Psychotropic substances mentioned as per Convention on Psychotropic Substances, 1971.

Appendix 4: Standard Bidding Documents for Procurement of Contraceptives through International Competitive Bidding

Overview of Standard Bidding Documents

The Standard Bidding Document package will usually consist of the following documents:

- Instructions to Bidder
- Bid Data Sheet
- General Conditions of Contract
- Special Conditions of Contract
- Technical Specifications
- Schedule of Requirements
- Special Forms, which can include:
    - Bid Submission Form
    - Price Schedules for Contraceptives
    - Manufacturer's Authorization
    - Bid Security Forms
    - Contract Form
    - Performance Guarantees
    - Product Certification Form

Samples of these documents are included in this Appendix.

The preparation of the bidding document is the responsibility of the Procuring Unit. The bidding document shall contain sufficient information to enable competition to take place among Bidders on the basis of complete, unbiased and objective terms.

Although preparation of the bidding document is the responsibility of the Procuring Unit, it shall be prepared in close collaboration with the beneficiary and end user.

The bidding document shall furnish all information necessary for a potential Bidder to prepare a bid. The bid document shall include:

a) Instructions for the preparation and submission of bids;
b) Information concerning the last date and place(s) for receipt of bids, including the date, hour and place of the bid opening with an announcement that the Bidder or their representative(s) may attend the bid opening;
c) bid submission sheet and sample formats for bid security, performance security and manufacturers' authorization, where applicable;
d) the number of copies to be submitted with the original bid;
e) conditions of contract, general and special;
f) specification of requirements, including time limit for delivery or completion;
g) evidence to be provided by the Bidder to demonstrate its qualifications for purposes of post-qualification verifications to be conducted by the Procuring Entity;
h) the period for which the bid shall remain valid;
i) the criteria to be taken into account in the evaluation of bids and award of contract and the way in which those criteria shall be evaluated;
j) a requirement that a Bidder shall, in the form specified in the bid documents, pledge not to engage in any corrupt, fraudulent, collusive or coercive;
k) a statement to the effect that the Procuring Entity may reject all bids at any time prior to the acceptance of a bid;
l) a provision for holding a pre-bid meeting with potential Bidders, where appropriate, in order to provide clarifications on the conditions of the bidding documents; and
m) a notification in the Bid Data Sheet concerning the process to be followed by a Bidder if it wishes to make any changes to its bid.

By way of further explanation of the above Regulations, Procuring Units shall comply with the following instructions when preparing bid documents.

Bidding documents shall be so worded that they permit and encourage open competition and shall set out clearly and precisely:

- the goods to be supplied;
- the place of delivery;
- the schedule for delivery;
- the minimum performance requirements;
- the warranty requirements; and
- any other relevant terms and conditions.

In addition, the bidding documents, where appropriate, shall define the tests, standards and methods that shall be used to judge the compliance of the contraceptives to be delivered with technical specifications.

The bidding document shall specify any criteria, in addition to price, which shall be taken into account in evaluating bids and how these shall be measured or otherwise evaluated.

If bids based upon alternative designs, materials, completion schedules, payment terms, etc., are permitted, the conditions for their acceptability and the method for their evaluation shall be stated in the bidding document.

All prospective Bidders shall be provided the same information and be assured of equal opportunities to obtain additional information promptly upon request.

Notes on the Instructions to Bidders (ITB) Form

This section of the Bidding Documents provides the information necessary for Bidders to prepare and submit responsive bids that meet the Purchaser's requirements. The ITB describe the critical steps of bid submission, opening and evaluation and the award of contract.

The ITB are to be used unchanged. The Bid Data Sheet (BDS) is designed to include provisions that supplement what is included in the ITB and provide the Contract-specific details needed for the bidding and evaluation process to be properly carried out. The Bid Data Sheet is specific to each procurement and must be filled in completely by the Purchaser.

Matters governing the performance of the Supplier, payments under the Contract, and affecting the risks, rights and obligations of the parties under the Contract during actual performance are not included in the ITB, but rather in the General Conditions of Contract and/or the Special Conditions of Contract Different sections of the Bidding Documents should not overlap or duplicate the coverage of a particular topic, to avoid creating ambiguity and/or contradictions.

The ITB and BDS do not form part of the final Contract.

Instructions to Bidders (ITB)

A. Introduction

1. Scope of Bid

1.1 The *Health and Population Welfare Departments*, Khyber Pakhtunkhwa, Peshawar, jointly invites bids from the eligible bidders for the supply of contraceptives (as specified in the Bid Data Sheet) described in the Schedule of Requirements. The name and identification number of the procurement has been provided in the Bid Data Sheet and in the SCC.

1.2 The terms "writing" and "days" wherever appearing in the bidding documents shall mean any type written, or printed communication, including e-mail, telex, cable and facsimile transmission, and "day" means calendar day. Singular also means plural.

2. Eligibility of Bidder

2.1 The Bidder can be a private, or public entity, or any combination of public or private entities including Joint Venture (JV), consortium with the formal intent, (substantiated with a letter of intent), to enter into an agreement or under an existing agreement

2.2 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;

2.3 A firm declared disqualified / blacklisted by any of the public sector organization in Pakistan shall be ineligible to bid for a contract during the period of embargo.

2.4 The Bidder and all parties constituting the Joint Venture (JV)/Consortium shall not have a conflict of interest. The Bidder shall be considered to have a conflict of interest, if they participated as a consultant in the preparation of the technical specifications of the goods that are the subject of this IFB. Where a firm, or a firm from the same economic or financial group, in addition to consulting, also has the capability to manufacture or supply goods or to construct works, that firm, or a firm from the same economic or financial group, cannot normally be a supplier of goods or works, if it provided consulting services for the contract corresponding to this IFB, unless it can be demonstrated that there is not a significant degree of common ownership, influence or control.

3. Qualifications of the Bidder

3.1 The Bidder shall provide documentary evidence to establish to the Procuring Agency's satisfaction that:

i. The Bidder has the financial, technical, and production capability necessary to perform the Contract, meets the qualification criteria specified in the Bid Data Sheet, and has a

successful performance history in accordance with criteria specified in the Bid Data Sheet.

ii. In case of national Bidders only manufacturers are allowed to participate in the bidding, an agent of manufacturer is not allowed to participate and bids from agents shall not be entertained.

iii. in the case of a foreign Bidder who is not doing business within the Procuring Agency's country (or for other reasons cannot itself carry out service / maintenance obligations), if awarded the Contract the Bidder's contractual obligations of after sales service and maintenance shall be, carried out by its authorized local representative possessing sufficient / satisfactory ability to carry out the Bidder's warranty obligations prescribed in the Conditions of Contract

4. Eligible Goods

4.1 All goods to be supplied under the contract to be financed by the Government of Khyber Pakhtunkhwa shall have as their origin in any country not restricted by the Government of Pakistan (Notified from time to time)

4.2 All goods to be supplied by international manufacturers must be WHO prequalified. National manufacturers will be exempted from WHO prequalification and will follow specifications as registered in DRAP for items to be quoted in this bidding. However, all batches/lots of local manufactured contraceptives would be tested from the Central Drug Testing Laboratory, Karachi, Pakistan, 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 accredited lab on the risk and cost of the Supplier.

5. Documents Establishing Conformity to Bidding Documents

5.1 The documentary evidence of conformity of the contraceptives to the Bidding Documents may be in the form of literature, drawings and data and shall consist of:

i. a detailed description of the essential technical and performance characteristics of the contraceptives;

ii. an item-by-item commentary on the Procuring Agency's Technical Specifications demonstrating substantial responsiveness of the contraceptives to those specifications, or a statement of deviations and exceptions to the provisions of the Technical Specifications;

iii. any other procurement-specific documentation requirement if mentioned in the Bid Data Sheet.

5.2 The contraceptives to be supplied under the Contract shall be registered if applicable with the Drug Regulatory Authority of Pakistan. A Bidder who has already registered its contraceptives by the time of bidding should submit a copy of the Registration Certificate with its bid.

In case the successful bidder fails to provide the requisite certificate of registration by the date of contract stipulated in the offer letter of contract execution, the bid shall stand rejected automatically and the bid security shall stand forfeited. No justification will thereupon be accepted.

6. Fraud and Corruption

6.1 It is the Government of Khyber Pakhtunkhwa's policy to require that bidders, suppliers and contractors and their sub-contractors observe the highest standard of ethics during the procurement and execution of such contracts. In pursuance of this policy, the following terms are defined:

i. "corrupt practice" is the offering, giving, receiving or soliciting, directly or indirectly, of anything of value to influence improperly the actions of another party;
ii. "fraudulent practice" is any act or omission, including a misrepresentation, that knowingly or recklessly misleads, or attempts to mislead, a party to obtain a financial or other benefit or to avoid an obligation;
iii. "collusive practice" is an arrangement between two or more parties designed to achieve an improper purpose, including to influence improperly the actions of another party;
iv. "coercive practice" is impairing or harming, or threatening to impair or harm, directly or indirectly, any party or the property of the party to influence improperly the actions of a party;
v. "obstructive practice" is deliberately destroying, falsifying, altering or concealing of evidence material to the investigation or making false statements to investigators in order to materially impede a Bank investigation into allegations of a corrupt, fraudulent, coercive or collusive practice; and/or threatening, harassing or intimidating any party to prevent it from disclosing its knowledge of matters relevant to the investigation or from pursuing the investigation.

6.2 the Procuring Agency will reject a proposal for award if it determines that the bidder recommended for award has, directly or through an representative, engaged in corrupt, fraudulent, collusive, coercive or obstructive practices in competing for the contract in question

6.3 the Procuring Agency will sanction a firm or individual, including declaring ineligible, either indefinitely or for a stated period of time, to

be awarded a contract if it, at any time, determines that the firm has, directly or through a Representative, engaged in corrupt, fraudulent, collusive, coercive or obstructive practices in competing for, or in executing, the contract; and

6.4 the Procuring Agency will have the right to require that a provision be included in bidding documents requiring bidders, suppliers and contractors and their sub-contractors to permit the Procuring Agency to inspect their accounts and records and other documents relating to the bid submission and contract performance and to have them audited by auditors appointed by the Procuring Agency

6.5 Furthermore, bidders shall be aware of the provision stated in Sub-Clauses 5.4 and 23 of the General Conditions of Contract

6.6 Indulgence in corruption and fraudulent practices is liable to result in rejection of Bids, cancellation of contracts, debarring and blacklisting of the Bidder, for a stated or indefinite period of time

7. Bidding for Selective Items

7.1 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.

8. One Bid per Bidder

8.1 An individual firm, bidder or joint venture shall be authorized to submit only one bid for one item. More than one bid for an item by any one of the above mentioned shall disqualify either of the one for that particular item bidding competition.

9. Cost of Bidding

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

10. Applicable Bidding Procedure

10.1 The bidding procedure shall be single stage two envelops procedure as provided under Rule 6 2 (b) of Khyber Pakhtunkhwa Procurement Rules, 2014 as mentioned in ITB 10.2. Bidders are advised also to refer to the Bid Data Sheet to confirm the Bidding procedure applicable in the instant bidding process.

10.2 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.*

x. 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.

B. The Bidding Documents

11. Content of Bidding Documents

11.1 The Bidding Documents are those stated below and should be read in conjunction with any addendum issued in accordance with ITB Clause 12.

i. Invitation for bid (IFB)
ii. Instructions to Bidders (ITB)
iii. Bid Data Sheet (BDS)
iv. General Conditions of Contract (GCC)
v. Special Conditions of Contract (SCC)
vi. Schedule of Requirements (including list of goods with quantities and delivery time)
vii. Technical Specifications
viii. Bid Forms (including Contract Agreement and sample format of all securities)

11.2 The "Invitation for Bids" is not a formal part of the Bidding Documents and is included as a reference only. In case of

discrepancies between the Invitation for Bid and the Bidding Documents listed in 11.1 above, the Bidding Documents shall take precedence.

11.3 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 any bid not substantially responsive to the Bidding Documents requirement shall be at the Bidder's risk and may result in the rejection of its bid.

12. Clarification of Bidding Documents

12.1 A prospective Bidder requiring any clarification of the Bidding Documents shall contact the Procuring Agency within 3 days of issuance of the bidding document, but ten days prior to the closing date of bid submission, in writing or by cable (for these ITB, the term "cable" is deemed to include electronic mail, telex, or facsimile) at the Procuring Agency's address indicated in the Bid Data Sheet.

The Procuring Agency will respond in writing to any request for clarification received within seven (7) calendar days of the receipt of the letter or prior to the deadline of submission of bids.

Copies of the Procuring Agency's response shall be sent to all prospective Bidders separately who have purchased the Bidding Documents, including a description of the inquiry but without identifying its source.

13. Amendment of Bidding Documents

13.1 At any time prior to the deadline for submission of bids, the Procuring Agency may amend the Bidding Documents by issuing Addenda.

Any addendum so issued shall be part of the Bidding Documents and shall be communicated in writing to all the bidders along with change in submission time if necessitate.

All Bidders so conveyed the change shall be required to immediately acknowledge receipt of the information and shall be presumed to have included the amendment while formulating the bid or have modified their bids accordingly.

C. Preparation of Bids

14. Language of Bids

14.1 All correspondences, communications, associated with preparation of Bids, clarifications, amendments, submissions shall be written in English. 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

English, in which case, for purposes of interpretation of the Bid, the said translation shall take precedence.

15. Documents Constituting the Bid

15.1 The Bid shall constitute the following documents:

i. Filled-in Form of Bid and Price Schedule, in accordance with the forms indicated in Section VII;
ii. Original form of bid security in accordance with the provisions of ITB Sub-Clause 19 (Bid Security);
iii. Written power of attorney authorizing the signatory of the bid to commit the Bidder;
iv. Documentary evidence establishing to the Procuring Agency's satisfaction, and in accordance with ITB Clause 3.1 that the Bidder is qualified to perform the Contract if its bid is accepted.
v. Any other documentation as requested in the Bid Data Sheet.

16. Bid Form

16.1 The Bidder shall complete the Bid Form as indicated in Section VII and the Price Schedule provided in the Bidding Documents.

17. Bid Price

17.1 Prices shall be quoted on DAP[5] basis in Pak Rupee OR Freely Convertible Currency. 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.

17.2 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.

17.3 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.

17.4 The Bidder's separation of price components in accordance with ITB Clause 17.2 above will be solely for the purpose of facilitating

[5] Incoterms 2010 will apply

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.

17.5 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. Pursuant to Sub-Clause 14.1 above, and 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.

17.6 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.

17.7 The Bidder should quote the prices of goods according to the technical specifications as provided in Section VI of this document. The technical specifications of goods, different from the required specifications, shall straightway be rejected.

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

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

17.10 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

17.11 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.

17.12 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.

18. Period of Validity of Bids

18.1 Bids shall remain valid for the period stipulated in the Bid Data Sheet which will commence from the date of bid opening. Any bid valid for a shorter period shall be rejected

18.2 In exceptional circumstances, prior to expiry of the original bid validity period, the Procuring Agency may request that the Bidders to extend the period of validity for a specified additional period. The request and the responses thereto shall be made in writing. A Bidder may refuse the request without forfeiture of its bid security. A Bidder agreeing to the request will not be required or permitted to modify its bid except to the extent of bid validity and bid security only,

19. Bid Security

19.1 The Bidder shall furnish, as part of its bid, a bid security as specified in the Bid Data Sheet. The amount of the Bid Security shall be as stipulated in the Bid Data Sheet.

19.2 The bid security shall remain valid for a period of 30 days beyond the validity period for the bid, and beyond any extension subsequently requested.

19.3 The bid security shall, at the Bidder's option, be in the form of either a bank guarantee, CDR (Call Deposit Receipt), Pay Order or banker's cheque from a scheduled bank in Pakistan., The format of the bank guarantee shall be in accordance with the forms included in the bidding documents. In case of foreign Bank Guarantee it must be attested by Embassy of Pakistan of respective country.

19.4 Any bid not accompanied by an acceptable bid security shall be rejected by the Procuring Agency being non-responsive. The bid security of a joint venture must be in the name of the principal partner of the joint venture

19.5 The bid securities of technically non-responsive Bidders will be returned as promptly as possible

19.6 The bid security of the successful Bidder will be returned when the Bidder has signed the Contract and furnished the required performance security

19.7 The bid security may be forfeited:

i. if the Bidder withdraws its bid, except as provided in ITB Sub-Clauses 18.2 or
ii. in the case of a successful bidder, if the Bidder fails within the specified time limit to:
   a) sign the contract; or
   b) furnish the required performance security.

20. Format and Signing of Bid

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

20.2 The original and all copies of the bid, each consisting of the documents listed in ITB Sub-Clause 11.1, shall be typed or written in indelible ink and shall be signed by the Bidder or a person or persons duly authorized to sign the Bid. The later authorization shall be indicated by written power of attorney, which pursuant to ITB Sub-Clause 11.1 shall accompany the bid

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

20.4 The Bid shall be accompanied by the original receipt for payment made for the purchase of the bidding document. In an event where the Bidder has downloaded the bidding document from the web site, he will be required to submit /exhibit the original payment receipt at the time of opening of the bids failing which his bid will not be opened.

D. Submission of Bids

21. Sealing and Marking of Bids

21.1 Bidders may submit their bids by hand or through registered post which should reach to the Procuring Agency within the given time. The bid received after the stipulated time shall stand rejected without any legal liability on the Procuring Agency.

i. The Bidder shall enclose the original and each copy of the bid, in separate sealed envelopes, duly marking the envelopes as "ORIGINAL" and "COPY". The envelopes containing the original and copies shall then be enclosed in another envelope.
ii. The envelopes shall be marked as "FINANCIAL PROPOSAL" and "TECHNICAL PROPOSAL" in bold and legible letters to avoid confusion. Similarly, the Bidder shall seal the proposals/ bids in separate envelopes. The envelopes shall then be sealed in an outer envelope.

21.2 The inner and outer envelopes shall:

i. bear the name and address of the Bidder;
ii. be addressed to the Procuring Agency at the address given in the Bid Data Sheet;
iii. Clearly mark inner envelopes separately as Financial and Technical Bids
iv. bear the specific identification of this bidding process indicated in the Bid Data Sheet, the Invitation for Bids (IFB) title and number indicated in the Bid Data Sheet; and
v. bear a statement "DO NOT OPEN BEFORE [date and time]" to be completed with the time and date specified in the Bid Data Sheet in accordance with ITB Sub-clause 22.1.

21.3 If the outer envelope is not sealed and marked as required by ITB Sub-Clause 21.1 the Procuring Agency will assume no responsibility for the misplacement or premature opening of the bid

21.4 In case the Bidder is bidding for more than one item, they will have to prepare separate price schedule for each item, seal them in separate envelops with naming of items. Envelops of each individual items will further be sealed in one envelope marked as "Financial Proposal". This arrangement will enable the Procuring Agency to return bid related to any item of any Bidder unopened in case the bid is declared as ineligible or non-responsive

22. Deadline for Submission of Bids

22.1 Bids must be received by the Procuring Agency at the address, date and time as specified in the Bid Data Sheet

23. Withdrawal of Bids

23.1 Once a bid is submitted it cannot be withdrawn.

E. Opening and Evaluation of Bids

24. Bid Opening

24.1 All bids received, shall be opened by the Procuring Agency publically in the presence of the Bidders or their representatives who choose to be present on the date, time and venue stipulated in the Bid Data Sheet.

24.2 The bids shall be opened in accordance with the procedure specified in Bid Data Sheet

24.3 All Bidders in attendance shall sign an attendance sheet.

24.4 The Procuring Agency shall open one Bid at a time and read out aloud its contents which may include name of the Bidder and items bided for. The Procuring Agency may choose to announce any other

details which it deems appropriate if not in conflict with the KPPR-2014, specifically Rule 37 (Opening of Bids)

24.5 Bids that are not opened and read out at bid opening shall not be considered further for bid evaluation irrespective of the circumstances.

24.6 The Procuring Agency shall have the minutes of the Bid opening (technical and when applicable financial) recorded.

24.7 The financial bid of the non-responsive bidder shall be returned unopened.

24.8 The financial bids without Bid Security being non-responsive shall be returned unannounced to the Bidders.

25. Clarification of Bids

25.1 During evaluation of the bids, the Procuring Agency may, at its discretion, ask the Bidder for a clarification of its bid. The request for clarification and the response shall be in writing, and no change in the prices or substance of the bid shall be sought, offered, or permitted. Except to correct arithmetic errors identified by the Procuring Agency in the evaluation of the bids, in accordance with ITB Sub-Clause 28.1

26. Confidentiality

26.1 Information relating to the examination, clarification, evaluation and comparison of bids, and recommendations for the award of a Contract shall not be disclosed to bidders or any other persons not officially concerned with such process until the notification of Contract award is made.

26.2 Any effort by the bidder to influence the Procuring Agency in the bid evaluation, bid comparison or contract award decisions may result in the rejection of the Bidder's bid. Canvassing by any Bidder at any stage of the bid evaluation is strictly prohibited. Any infringement thereto shall lead to rejection of the bid

26.3 From the time of bid opening to the time of Contract award, if any Bidder wishes to contact the Procuring Agency on any matter related to its bid or intends to bring additional information to the notice of the Procuring Agency, it may do so in writing.

27. Examination of Bids and Determination of Responsiveness

27.1 The Procuring Agency shall examine the bids to ascertain as to whether they are complete, free of any computational errors, all required sureties have been attached, all documents have been properly signed, and the bids are generally in order. In the case the bidding process is conducted through prequalified bidders Procuring Agency shall ensure that bidding documents have been issued to the prequalified bidders only and each bid received is from a prequalified Bidder.

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

27.3 Prior to the detailed evaluation, the Procuring Agency shall determine whether each bid is of acceptable quality, is complete and is substantially responsive to the Bidding Documents. For purposes of this determination, a substantially responsive bid is one that conforms to all the terms, conditions, and specifications of the Bidding Documents without material deviations, exceptions, objections, conditionality, or reservations. A material deviation, exception, objection, conditionality, or reservation is one that:

i. changes the substance of the bid
ii. limits in any substantial way the scope, quality or performance of the products and related Services;
iii. limits, in any substantial way that is inconsistent with the Bidding Documents, the Procuring Agency's rights or the successful Bidder's obligations under the Contract; and
iv. the acceptance of which would unfairly affect the competitive position of other Bidders who have submitted substantially responsive bids.

27.4 If a bid is not substantially responsive, it shall be rejected by the Procuring Agency and may not subsequently be made responsive by the Bidder by correction of the nonconformity. The Procuring Agency's determination of a bid's responsiveness is to be based on the content of the bid itself.

28. Correction of Errors

28.1 In the financial bids the arithmetical errors shall be rectified on the following basis.

a) If there is a discrepancy between the unit price and the total price that is obtained by multiplying the unit price and quantity, the unit price shall prevail, and the total price shall be corrected.

b) If the Bidder does not accept the correction of the errors, its bid shall be rejected, and its Bid Security shall be forfeited.

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

29. Evaluation of Bids

29.1 The Procuring Agency shall evaluate and compare the bids that have been determined to be substantially responsive in accordance with ITB Clause 27 above.

29.2 All bids shall be evaluated in accordance with the Evaluation Criteria and other terms and conditions set forth in the bidding documents

29.3 For the purposes of comparison of bids quoted in different currencies, the price shall be converted into Pak Rupees. The rate of exchange shall be the selling rate, prevailing on the date of opening of bids specified in the bidding documents, as notified by the State Bank of Pakistan on that day.

30. Domestic Preference

30.1 Domestic preference in terms of allowable price differentiation is not applicable in this invitation for bid as national manufacturers are exempted from WHO prequalification requirement for requested products. In case where the lowest evaluated bid price of a national manufacturer and the lowest evaluated price of an international manufacturer are equal upon full evaluation, preference will be given to the local manufacturer.

31. Qualification of Bidder

31.1 The Procuring Agency, at any stage of the procurement proceedings, having credible reasons for or prima facie evidence of any defect in Bidder's capacities may require the Bidder to provide information concerning their professional, technical, financial, legal or managerial competence. Such clarification shall form part of the records of that procurement proceeding

31.2 The Procuring Agency shall disqualify a Bidder if it finds, at any time, that the information submitted by it concerning it's qualification as Bidder is false, fake and materially incorrect.

32 Announcement of Evaluation Report

32.1 The Procuring Agency shall announce the results of the bid evaluation both technical and financial in the form of a report, as required by Rule 45 of the KPPR-2014 giving justification for acceptance or rejection of bids at least ten days prior to the award of procurement Contract. The unsuccessful bidder may file their grievance petition if any within ten days of the announcement of the evaluation report as required by section 35 of KPPRA Act 2012.

F. Award of Contract

33. Award of Contract	33.1	The Procuring Agency will award the Contract to the Bidder whose bid has been determined to be the lowest evaluated bid, , within the original or extended period of bid validity
34. Procuring Agency's Right to Vary Quantities at Time of Award	34.1	The Procuring Agency reserves the right to increase or decrease the quantities of the goods being procured to the extent as specified in the Bid Data Sheet at the time of Contract award. The qualified bidder shall be bound to supply the requisite quantity as per approved evaluated rate and without any change in terms and conditions of the bidding document
35. Notification of Award	35.1	Prior to the expiration of the period of bid validity, the Procuring Agency will notify the successful Bidder in writing by registered letter, that its bid has been accepted.
	35.2	The notification of award will constitute the formation of the Contract between the Procuring Agency and the successful Bidder
	35.3	The enforcement of the Contract shall be governed by Rule 46 of the KPPR-2014
	35.4	Upon the successful Bidder's furnishing of the signed Contract Form and performance security pursuant to ITB Clause 37, the Procuring Agency will immediately execute the contract.
36. Limitation on Negotiations	36.1	There shall be no negotiation on price.
37. Performance Guarantee	37.1	On the date of signing of Contract, the successful Bidder shall furnish a Performance Guarantee, in the form and manner prescribed by the Procuring Agency as specified in the bidding document
	37.2	The Bid Security submitted by the bidder at the time of submitting its bid shall be returned to the successful Bidder upon submission of Performance Guarantee
	37.3	Failure to provide a Performance Guarantee by the Bidder is a sufficient ground for annulment of the award and forfeiture of Bid Security. In such event the Procuring Agency may award the contract to the next lowest evaluated bidder or call for new bid
38. Signing of Contract	38.1	The contract with the successful bidder shall be executed as per call letter for contract execution.

38.2 The Contract shall become effective from the date of affixation of signature by the Procuring Agency and the successful Bidder on the Contract document,

39. Integrity Pact

39.1 The Bidder shall sign and stamp the Integrity Pact provided in Section VII for all Provincial Government procurement contracts exceeding Rupees ten million. Failure to provide the Integrity Pact shall make the bidder non-responsive.

Notes on the Bid Data Sheet Form

The Bid Data Sheet is intended to assist the Purchaser in providing the specific information in relation to corresponding clauses in the Instructions to Bidders included in Section I and has to be prepared for each specific procurement.

The Purchaser should specify in the Bid Data Sheet information and requirements specific to the circumstances of the Purchaser, the processing of the procurement, the applicable rules regarding bid price and currency and the bid evaluation criteria that will apply to the bids. In preparing Section II, the following aspects should be checked:

a. The correct version of the Bid Data Sheet must be used as a base, dependent upon the type of contraceptives being procured. For example, if changes or additions are made to the Bid Data Sheet it may require changes to the corresponding SCC.
b. Information that specifies and complements provisions of Section I, ITB, must be incorporated.
c. Amendments and/or supplements, if any, to provisions of Section I, ITB, as required by the circumstances of the specific procurement, must also be incorporated.

The date for the bid opening should be the same as specified for the bid submission deadline, and the time should be shortly thereafter, to minimize possible complaints regarding insecure storage arrangements. If the address for bid submission and the place of bid opening are not the same, adequate time between bid submission deadline and bid opening times should be allowed to accommodate physically moving the bids from one site to the other. However, this delay must be kept to a minimum and reflect only the requirements of logistics, say, no more than two hours.

The currency chosen for the purpose of converting to a common currency is: [specify either: the local currency, or a convertible currency commonly used for procurement of contraceptives, for example, U.S. dollars].

The source of exchange rate is: [insert: publication, name of bank, etc.].

Note: If the common currency is other than the local currency, for example, U.S. dollars, indicate the name of an internationally circulated newspaper that lists daily currency selling exchange rates which will be used for converting prices in foreign currencies. For prices in local currency, and if the common currency selected above is the local currency, specify either the Central Bank or a commercial bank in the Purchaser's country, and identify the publication where the specified rates are published.

The date of exchange rate determination is: [select: a date that shall not be earlier than four (4) weeks prior to the original deadline for the receipt of bids as specified for ITB Sub-Clause 23.1, and no later than the expiration of the original bid validity period].

Bid Data Sheet

The following specific data for the contraceptives to be procured shall complement, supplement or amend the provisions in the Instructions to Bidders (ITB). Whenever there is a conflict, the provisions in the Bid Data Sheet (BDS) shall prevail over those in the ITB.

ITB Ref	Description	Detail
	Commencement of sale of Bidding Document	From the date of publishing of IFB
ITB Clause22.1	Last date & time of sale of Bidding Document	(*insert date*) DD-MM-YYYY Till 00:00 AM
ITB Clause 1.1	Bid title and reference number	Joint Procurement of Contraceptive for Health and Population Welfare Departments
ITB Clause 3.1	Qualifications of Bidder	See Bid Forms 3(A), 4 and all others in Section VII. Bid Forms
ITB Clause 5.1	Documents Establishing Conformity to Bidding Documents	see list of documents at ITB 5.1 & 5.2
ITB Clause 10.1	Bidding procedure	Single stage – Two Envelop procedure as detailed at ITB 10.1 & 10.2
ITB Clause 12.1	Clarification of Bidding Documents	(*insert designation & address*) Phone: (insert number)
ITB Clause 14.1	Language of bid	English
ITB Clause 17	Bid Price: Final Destination	DAP - Central Warehouse Karachi
ITB Clause 17.5	Bid Price	Price shall be fixed
ITB Clause 17.10	Bid Price	Supplier must quote for the full quantities requested
ITB Clause 18.1	Bid validity period	120 Days
ITB Clause 19.1	Amount of bid security	2% of the total bid value
ITB Clause 20.1	Number of bid copies	One original set and *1* copy
ITB Clause 21.2.ii	Marking of Bids	(PA to Director Health Services)
ITB Clause 21.2.iv	Marking of the Bids	Joint Procurement of Contraceptive for Health and Population Welfare Departments
ITB Clause 22.1	Last date and time for the receipt of bidding document	(*insert date*) DD-MM-YYYY 11:00 am
ITB Clause 24.1	Date, time and venue of opening of technical bids	(*insert date*) DD-MM-YYYY 11:00 am (*insert place & address*)
ITB Clause 33.1	Right to Vary Quantities at Time of Award	

Bid Data Sheet

Pharmaceuticals

(Additional Clauses)

[Note: The below data should be included in the Bid Data Sheet used in Bidding Documents for the procurement of pharmaceuticals.]

ITB 4.2

[Sample clauses]

The contraceptives offered should meet the specified pharmacopoeial standards as stated in the Technical Specification. If the contraceptives offered are not included in one of the specified pharmacopoeias (e.g., the case of a new drug), the Bidder will provide testing protocols and alternative reference standards.

ITB 3.1

Documentary evidence of the Bidder's qualifications to perform the Contract if its bid is accepted:

The Bidder will submit the following additional information:

(f) has a Good Distribution Practice (GDP) Certificate where appropriate.
(g) list of pharmaceuticals being manufactured by the Bidder with product registration/license number and date.
(h) a Certificate of Pharmaceutical Product as recommended by the WHO for each item offered.

Technical Evaluation Criteria

Technical Evaluation Criteria			Compliance Requirements			Documentation
No.	**Subject**	**Requirement**	**Single Entity**	**Joint Venture / Consortium**		**Submission Requirements/Marks**
				All Parties Combined	**Each Partner**	
1. Compulsory/Primary Criteria-(Bidders qualifying the Compulsory Evaluation Criteria shall be eligible for detail evaluation of their technical proposals).						
1.1	**Nationality**	Bidders of a country may be excluded from bidding if as a matter of law, the Government of Pakistan prohibits commercial relation with that country. Reference ITB Clause 2.2	Must meet requirement	Existing or intended JV/consortium must meet requirement	Must meet requirement	To meet this criterion bidders need to submit following forms given in Section VII: • Bid Form I & Form ELI-1.1
1.2	**Conflict of Interest**	No conflicts of interest in accordance with ITB Clause 2.4	Must meet requirement	Existing or intended JV/consortium must meet requirement	Must meet requirement	To meet this criterion bidders need to submit following forms given in Section VII: • Bid Form 1 & Form ELI-1.1
1.3	**Not Declared Ineligible**	a)Not having been declared ineligible by any of the public sector organization in Pakistan, as described in ITB Clause 2.3 b) Not having been involved in any litigation during last three years. In case yes, provide details	Must meet requirement	Existing JV/consortium must meet requirement	Must meet requirement	To meet this criterion bidders need to submit following forms given in Section VII: • Form ELI-1.2 (Affidavit)
1.4	**WHO Prequalification**	Only for products not manufactured in Pakistan, as per ITB Clause 4.2	Must meet requirement	Must meet requirement	N/A	To meet this criterion bidders need to submit following forms given in Section VII: • Form ELI – 1.3
1.5	**Lab Testing of Locally Manufactured Contraceptives**	An undertaking by local manufacturer that "in case of any doubt on quality of supplied contraceptives the Procuring Agency reserves the right to send maximum up to five batches/lots to WHO accredited labs for quality assurance, on the risk and cost of	Must meet requirement	Must meet requirement	N/A	To meet this criterion bidders need to submit following Affidavit: • Affidavit

Technical Evaluation Criteria			**Compliance Requirements**			**Documentation**
No.	**Subject**	**Requirement**	**Single Entity**	**Joint Venture / Consortium**		**Submission Requirements/Marks**
				All Parties Combined	**Each Partner**	
		the local manufacturer/Supplier in addition to contraceptive standard testing at Central Drug Testing Laboratory, Karachi as per Drug Act standard policies.				
1.6	**cGMP/CE/FDA/ Equal Manufacturer's Country Quality Assurance Certificate**	The Bidder or his principal manufacture will submit valid cGMP/CE/FDA or Manufacturer's Country Quality Assurance Certificate showing that the bidder follows quality manufacturing practices	Must meet requirement	Must meet requirement	N/A	To meet this criterion bidders need to submit following certificate: • Copy of Cgmp/CE/FDA/ Manufacturer's Country Quality Assurance Certificate.
1.7	**DRAP Registration Certificate**	The foreign Bidders shall be required to submit proof of registration application with DRAP Pakistan (If applicable)	Must meet requirement	Must meet requirement	N/A	To meet this criterion bidders need to submit following certificate: • Copy of DRAP registration Certificate (if applicable)
1.8	**Manufacturing License**	The Bidder will submit the Valid Manufacturing License	Must meet requirement	Must meet requirement	N/A	To meet this criterion bidders need to submit following license: • Copy of Manufacturing License

Technical Evaluation Criteria			**Compliance Requirements**			**Documentation**
No.	**Subject**	**Requirement**	**Single Entity**	**Joint Venture / Consortium**		**Submission Requirements/Marks**
				All Parties Combined	**Each Partner**	
2. Secondary Evolution Criteria-Total Marks 50, Minimum Passing Marks 30 (60 %)						
2.1	**Financial Performance**	Submission of audited balance sheets along with Income Tax Returns for up to last 3 years.	Must meet requirement	Must meet requirement	N/A	Maximum Marks for this criterion is 10, • Documents submitted for last 3 years= 10 Marks • Documents submitted for less than 3 years= 07 Marks Document Submission Requirement is Section VII, Form FIN – 2.1 (a) with attachments
2.2	**Annual Sales Turnover**	Average annual turnover/sales value should be at least PKR Rs. 10 million or equal during the last 3 years (three years)	Must meet requirement	Must meet requirement	N/A	Maximum Marks for this criterion is 10, • Documents showing average sales turnover of quoted item as PKR Rs. 10 Million for last 3 years= 05 Marks • Documents showing average sales turnover of quoted item above PKR Rs. 10 Million for last 3 years= 10 Marks • Documents showing average sales turnover of quoted items less than PKR Rs. 10 Million for last 3 years= 0 Marks and the bidder shall stand disqualified from bidding. Documents submission requirement is Section VII, Form FIN – 2.1 (b) with attachments

Technical Evaluation Criteria			**Compliance Requirements**			**Documentation**
No.	**Subject**	**Requirement**	**Single Entity**	**Joint Venture / Consortium**		**Submission Requirements/Marks**
				All Parties Combined	**Each Partner**	
2.3	**Specific Supplies Experience**	Participation as supplier/manufacturer in quoted items within the last two years in public or private tenders.	Must meet requirement	Must meet requirement	N/A	Maximum Marks for this criterion is10, • Documents showing participation in one Public/Private tender in last 2 years= 05 Marks • Documents showing participation in more than one Public/Private tenders in last 2 years= 10 Marks Documents submission requirement in Section VII, Form EXP- 3.2 with Attachments
2.4	**Production Capacity**	Annual Production Capacity of the Bidder or his principal manufacturer in quoted item should be at least equal or above than the advertised quantity.	Must meet requirement	Must meet requirement	N/A	Maximum Marks for this criterion is10, • Documents showing Annual Production Capacity i.e. equal to the advertised quantity = 05 Marks • Documents showing Annual Production Capacity double or above to the advertised quantity = 10 Marks Documents submission requirement is Section VII, Form EXP-3.3 with attachments.
2.5	**ISO Certification**	The Bidder or his principal manufacturer will submit valid ISO certification	Must meet requirement	Must meet requirement	N/A	Maximum Marks for this criterion is10, • Copy of valid ISO submitted = 10 Documents submission requirement is ISO valid ISO certificate. Total Marks: 50, Passing Marks 30 Marks.

General Conditions of Contract (GCC)

Notes on the General Conditions of Contract

The General Conditions of Contract (GCC), read in conjunction with the Special Conditions of Contract (SCC) and other documents listed in the Contract Agreement, should be a complete document expressing all the rights and obligations of the parties.

GCC must remain unaltered. Contract-specific information, deletions, extensions and modifications to the GCC shall be introduced only through the SCC.

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 (provincial and district Health department) and the Supplier, as recorded in the Agreement 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 those supplies 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 above goods, such as printing of special instructions on the label and packing, design and logo of the government of Khyber Pakhtunkhwa, transportation of goods upto the desired destinations 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 Special Conditions of the Contract.

(g) "The Procuring Agency" means the Government of Khyber Pakhtunkhwa, Health and

Population Welfare Department Peshawar.

(h) "The Supplier" means the individual or firm supplying the goods under this Contract.

(i) "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. Source of Import

3.1 All goods and related services to be supplied under the contract that are required to be imported in Pakistan shall have their origin in eligible source countries as prescribed by the commercial policies of the Government of Pakistan and all expenditures made under the contract shall be limited to such goods and services.

3.2 For purposes of this clause, "origin" means the place where the goods are produced, or the place from which the related services are supplied. Goods are produced when, through manufacturing or processing.

4. Standards

4.1 The goods supplied under this Contract shall conform to the standards mentioned in the Technical Specifications.

4.2 In consideration of the payments to be made by the Procuring Agency to the Supplier as hereinafter mentioned, the Supplier shall be required to provide the Goods and Services and to remedy defects therein in conformity in all respects with the provisions of this Contract.

4.3 If the Supplier provide substandard item and fail to provide the fresh supply, the procurement shall be made on the risk and cost of the supplier by the procuring agency.

4.4 In case of supply of substandard product the cost associated with disposal/destruction or handling cost shall be borne by the Supplier.

5. Use of Contract Documents and Information

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 authorized for this. 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 except for purposes of performing the Contract.

5.3 Any document, other than the Contract itself, enumerated in GCC 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.

6. Patent Rights

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 country.

7. Submission of Samples

7.1 Before commencing supplies, the Supplier shall provide samples free of cost, if and as specified in the Schedule of Requirements of the product to the designated office or staff, as the case may be.

8. Ensuring storage arrangements

8.1 To ensure storage arrangements for the intended supplies, the Supplier shall inform the Procuring Agency at least 7 working days in advance. However, in case no space is available at the Procuring Agency's premises at the time of supply, the Procuring Agency shall, at least 02 working days prior to such situation, shall inform the Supplier, in writing, of the possible time frame of availability of space by which the supplies can be made. In case the Supplier abides by the given time frame it shall not be penalized for delay.

9. Inspections and Tests

9.1 The Procuring Agency or its representative shall have the right to inspect and / or to test the goods in accordance with the procedure given in the SCC to confirm their conformity to the Contract specifications at no extra cost to the Procuring Agency.

9.2 All costs associated with testing shall be borne by the Supplier.

9.3 The Procuring Agency's right to inspect, test and, where necessary, reject the goods after the goods either at Supplier's premises or upon arrival at Procuring Agency's destinations 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 delivery from the point of Supply or manufacturing.

9.4 Nothing in GCC Clause 9 shall in any way release the Supplier from any warranty or other obligations under this Contract.

10. Packing

10.1 The Supplier shall provide such packing of the contraceptives 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 contraceptives' final destination and the absence of heavy handling facilities at all points in transit.

10.2 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 the SCC or Technical Specifications, and in any subsequent instructions ordered by the Procuring Agency

11. Delivery and Documents

11.1 The Supplier in accordance with the terms and manner specified in the Schedule of Requirements shall make delivery of the goods.

11.2 The Supplier shall furnish all necessary documentation necessary for completion of the delivery, at the time of delivery and in the manner prescribed.

11.3 The goods supplied under the Contract shall be Delivered at Place (DAP) under which risk is transferred to the buyer after the Goods having been delivered

12. Insurance

12.1 The supplier shall be responsible for arranging shipment of goods on DAP basis. Responsibility for marine insurance to be agreed in the contract.

13. Transportation

13.1 The Supplier shall arrange such transportation of the goods 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

13.2 All costs associated with the transportation of the goods subject to this contract shall be borne by the Supplier.

14. Incidental Services

14.1 The Supplier shall be required to provide the incidental services as specified in the SCC and the cost of which is included in the total bid price.

15. Warranty

15.1 All products must be of fresh manufacture and must bear the dates of manufacture and expiry.

The Supplier further warrants that all products supplied under the Contract that have shelf lives will have remaining a minimum of 75% of the specified shelf life upon delivery at port/airport of entry for products with a shelf life of more than two years and three-fourths (3/4) for products with a shelf life of two years or less, unless otherwise specified in the SCC or technical specifications; have "overages" within the ranges set forth in the Technical

Specifications, where applicable; are not subject to recall by the applicable regulatory authority due to unacceptable quality or an adverse drug reaction; and in every other respect will fully comply in all respects with the Technical Specifications and with the conditions laid down in the Contract.

15.2 The Procuring Agency shall have the right to make claims under the above warranty for three months after the products have been delivered to the final destination indicated in the Contract. Upon receipt of a written notice from the Procuring Agency, the Supplier shall, promptly, replace the defective products without cost to the Procuring Agency. The Supplier will be required to remove, at his own risk and cost, the defective products once the replacement contraceptives have been delivered

15.3 In case of supply of substandard quality, declared by the Testing Laboratory, the supplier shall be bound to replace the substandard goods. The procuring agency shall reserve the right to proceed against the supplier on account of supply of substandard goods, as per law.

15.4 In the event of a dispute by the Supplier, a counter analysis will be carried out on the manufacturer's retained samples by an independent neutral laboratory agreed by both the Procuring Agency and the Supplier. If the counter analysis confirms the defect, the cost of such analysis will be borne by the Supplier as well as the replacement and disposal of the defective products. The procuring agency shall reserve the right to proceed against the supplier on account of supply of substandard goods, as per law.

16. Payment

16.1 The Respective Procuring Agency shall make payments to the Supplier in accordance with the conditions set forth in the Payment Schedule agreed and annexed to this contract.

16.2 The currency or currencies in which payment is made to the Supplier under this Contract shall be specified in the SCC subject to the following general principle: Payment will be made in the currency or currencies; in which the payment has been requested in the Supplier's bid.

16.3 All payments shall be made in the currency or currencies specified in the SCC pursuant to GCC 15.4.

17. Prices

17.1 Prices charged by the Supplier for goods delivered under the Contract shall not vary from the prices quoted by the Supplier in its bid and shall remain the same till the expiry of the contract.

18. Contract Amendments

18.1 No variation in or modification of the terms of the Contract shall be made unless supported by force majeure on either of the party.

19. Assignment

19.1 The Supplier shall not assign, in whole or in part, its obligations to perform under this Contract,.

20. Subcontracts

20.1 The Supplier shall not be allowed to sublet and award subcontracts under this Contract.

21. Delays in the Supplier's Performance

21.1 Delivery of the goods shall be made by the Supplier in accordance with the timeline prescribed by the Procuring Agency in the Schedule of Requirements.

21.2 If at any time during performance of the Contract, the Supplier encounters conditions impeding timely delivery of the goods, the Supplier shall promptly notify the Procuring Agency in writing of the fact of the delay, it's 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 an amendment to the Contract.

21.3 Except as provided under GCC Clause 24, a delay by the Supplier in the performance of its delivery obligations shall render the Supplier liable to the imposition of liquidated damages as prescribed in the SCC, unless the parties to this contract mutually agree for extension of time.

22. Termination for Default

22.1 The Procuring Agency, without prejudice to any other remedy for breach of Contract, by written notice of default sent to the Supplier, shall terminate the Contract: in case:

(a) if the Supplier fails to deliver any or all installments of the goods within the period(s) specified in the Contract and subsequent purchase order, or within any extension thereof granted by the Procuring Agency pursuant to GCC Clause 21; 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, fraudulent or collusive practices in competing for or in executing the Contract.

For the purpose of this clause Corrupt, fraudulent and collusive practices means:

the offering, giving, receiving, or soliciting of anything of value to influence the action of a public official or the supplier or contractor in the procurement process or in contract execution to the detriment of the Procuring agencies; or misrepresentation of facts in order to influence a procurement process or the execution of a contract, collusive practices among bidders (prior to or after bid submission) designed to establish bid prices at artificial, non-competitive levels and to deprive the Procuring agencies of the benefits of free and open competition and any request for, or solicitation of anything of value by any public official in the course of the exercise of his duty"

The PA may also proceed against the supplier on account of its default which may result forfeiture of the performance guaranty and the blacklisting of the supplier

23. Force Majeure

23.1 Notwithstanding the provisions of GCC Clauses 21 and 22, the Supplier shall not be liable for forfeiture of its Performance Guaranty, or termination/ blacklisting for default if and to the extent that it's delay in performance or other failure to perform its obligations under the Contract is the result of an event of Force Majeure.

23.2 For the purposes of this clause Force Majeure means an act of God or an event beyond the control of the Supplier and not involving the Supplier's fault or negligence directly or indirectly purporting to miss planning, mismanagement and/or lack of foresight to handle the situation. Such events may include but are not restricted to acts of the Procuring Agency in its sovereign capacity, wars or revolutions, fires, floods, earthquakes, strikes, epidemics, quarantine restrictions and freight embargoes.

23.3 If a Force Majeure situation arises, the Supplier shall promptly notify the Procuring Agency in writing with sufficient and valid evidence of such condition and the cause thereof. The Procuring Agency shall examine the merits of the case and all reasonable alternative means for completion of purchase order under the Contract and inform the Supplier of its findings promptly.

23.4 Unless Procuring Agency informs the Supplier in writing of its agreement on the application of force majeure, the Supplier shall continue to perform its obligations under the Contract as far as is reasonably possible.

24. Termination for Insolvency

24.1 In case the Supplier becomes bankrupt or insolvent, the Procuring Agency may at any time terminate the Contract by giving written notice of reasonable time which will not be less than 15 days to the Supplier In this event, termination shall be without compensation to the Supplier, provided that such termination shall not prejudice or affect any right of action or remedy which has accrued or shall accrue thereafter to the Parties.

25. Termination for Convenience

25.1 The Procuring Agency, by written notice sent to the Supplier, may terminate the Contract, in whole or in part, at any time on administrative grounds. The notice of termination shall specifically mention, the extent to which performance of the Supplier under the Contract is terminated and the date upon which such termination becomes effective.

25.2 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:

(a) to have any portion completed and delivered at the Contract terms and prices; and/or

(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.

26. Arbitration and Resolution of Disputes

26.1 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.

26.2 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 to the Arbitrator for resolution through arbitration

26.3 In case of any dispute concerning the interpretation and/or application of this Contract shall be settled through arbitration under the Arbitration Act of 1940 (As amended from time to time).

Administrative secretary of the PA shall act as an arbitrator.

27. Limitation of Liability

27.1 Except in cases of criminal negligence or willful misconduct, and in the case of infringement pursuant to Clause 7,

(a) the Supplier shall not be liable to the Procuring Agency, whether in contract, tort or otherwise, for any indirect or consequential loss or damage, loss of use, loss of production or loss of profits or interest costs, provided that this exclusion shall not apply to any obligation of the Supplier to pay liquidated damages to the Procuring Agency; and

(b) the aggregate liability of the Supplier to the Procuring Agency, whether under the Contract, in tort or otherwise, shall not exceed the total Contract Price, provided that this limitation shall not apply to the cost of replacing defective goods.

28. Governing Language

28.1 The Contract shall be written in English language. Subject to GCC Clause 31, the version of the Contract written in the specified language shall govern its interpretation. All correspondence and other documents pertaining to the Contract, which are exchanged by the Parties, shall be written in English.

29. Applicable Law

29.1 This Contract shall be governed by the Laws of Pakistan and the courts of Pakistan shall have exclusive jurisdiction.

30. Notices

30.1 Any Notice given by one party to the other pursuant to the provision of the Contract shall be sent to the other party in writing and on the others address specified in SCC.

30.2 A notice shall be effective when delivered or on the notice's effective date, whichever is later.

31. Taxation

31.1 All taxation, whether International, Federal, Provincial or Local, shall be borne by the Supplier.

Notes on the Special Conditions of Contract

Similar to the Bid Data Sheet, the clauses in the Special Conditions of Contract are intended to assist the Purchaser in providing Contract-specific information in relation to corresponding clauses in the General Conditions of Contract (GCC).

The Special Conditions of Contract complement the GCC, specifying contractual requirements linked to the special circumstances of the Purchaser, the Purchaser's country, the sector and the contraceptives purchased. In preparing this section, the following aspects should be checked:

(a) Information that complements provisions of the GCC must be incorporated in the SCC.

(b) Amendments and/or supplements to provisions of the GCC, as necessitated by the circumstances of the specific purchase, must also be incorporated.

Note

The procuring unit cannot submit the contract for relevant authority signature until registration of the contraceptives has been completed. It is critically important for the Procurement Unit to be aware of registration status and to monitor progress of registration since Drugs Regulatory registration procedures can take time and delay contract signing which, in turn, can delay the delivery date of the contraceptives.

Special Conditions of Contract (SCC)

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 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 worth of one hundred rupees or any amount required as per the law.

2. Supplier's declaration

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

2.2 *[The Supplier]* certifies at 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

2.3 *[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 void able at the option of Procuring Agency.

2.4 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 time 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

2.5 In case of any dispute concerning the interpretation and/or application of this Contract shall be settled through arbitration. 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

3. Price

3.1 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 5(A)

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

3.3 The Unit Cost agreed in the Price Schedule Bid form 5(A) , is inclusive of all taxation and costs associated with transportation and other agreed incidental costs

4. Payments

4.1 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

4.2 (I) In case of imported items the payment will be made through Letter of Credit at sight as per fulfillment of requirements mentioned in the bidding documents. 80 % of the contract value shall be made upon receipt of standard shipping documents/Bill of lading, insurance certificate, inspection certificates of manufacturer, Batch/Lot testing report from WHO accredited lab, compliance of quality standards etc. Whereas 20% remaining payment shall be made upon successful completion of Contraceptives Testing and the presentation of the same at the Bank.

(ii) In case of locally manufactured items 100% payment shall be made upon receipt of successful delivery and upon receipt of successful completion of contraceptives testing issued by the respective procuring agencies.

4.3 All payments to the Supplier shall be made by the respective procuring agency in accordance with the agreed Payment Schedule upon satisfactory completion of delivery and fulfillment of documentary and Codal formalities highlighted in the Payment Schedule.

5. Performance Guarantee

5.1 The Supplier, 07 days prior to signing of this contract, shall provide to the respective Procuring Agency separately a Performance Guarantee 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 and within 30 days after the final payment

5.2 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

5.3 Failure to submit a Performance Guarantee shall result into forfeiture of Bid Security and Cancellation of Contract and initiation of blacklisting procedure.

6. Penalties/ Liquidated Damages

6.1 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.

6.4 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.

Special Conditions of Contract: Pharmaceuticals

(Additional Clauses)

The below data should be included in the Special Conditions of Contract used in Bidding Documents for the procurement of pharmaceuticals.

For contraceptives supplied from abroad:

- One original of the Certificate of Pharmaceutical Product as recommended by the WHO for each of the items supplied.
- Certificate of quality control test results in conformity with the World Health Organization "Certification Scheme on the Quality of Pharmaceutical Products Moving in International Trade" stating quantitative assays, chemical analysis, sterility, pyrogen content, uniformity, microbial limit and other tests as appropriate to the contraceptives.
- Original copy of the certificate of weight issued by the port authority/licensed authority and six copies.

Special Conditions of Contract: Condoms

The following Special Conditions of Contract shall supplement the General Conditions of Contract in the procurement of condoms. 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.

The Supplier shall test batches of contraceptives ready for shipment in accordance with the WHO specification. The size of the sample for testing will be calculated by reference to ISO2859-1. With each consignment, the Supplier must provide a certificate of quality control test results in conformity with the standards laid down in ISO 2859-1 and in accordance with the general sampling levels appropriate to each feature as necessary. The Supplier will bear the cost of such tests.

For contraceptives supplied from abroad:

- original copy of quality control tests for each consignment as stated in SCC 8 above.
- original copy of the certificate of inspection furnished to Supplier by nominated inspection agency and six copies [where separate inspection is required].

For contraceptives from within the Purchaser's country:

- (ix) certificate of in-house analysis.

Notes for Preparing the Schedule of Requirements

The Schedule of Requirements provides a concise description of each product and the quantity required, along with any technical specifications unique to that item. If it can be printed with sufficient space for Suppliers to enter offers, having Suppliers use this space for bids greatly simplifies the collation of offers. Sufficient space should be provided so that the Supplier can enter all relevant information, including the name of the original manufacturer.

The Schedule of Requirements should include the international non-proprietary name (INN) or generic name (for combination product, the name of each generic component), the strength in metric units for each component, the basic unit (tablet, capsule, vial, bottle), the package size and the number of packages needed. Some Schedules of Requirements list both the total number of packages and the total number of basic units needed to avoid misunderstanding and to allow for the possibility that a Supplier may offer a different (but acceptable) package size representing the same number of basic units. The schedule of requirements should specify whether the listed package sizes are the only ones acceptable.

The delivery schedule expressed as weeks stipulates hereafter a delivery date that is the date of delivery (i) at EXW premises, or (ii) to the carrier at the port of shipment when the Contract is placed on FOB or CIF terms or (iii) to the first carrier when the Contract is placed on FCA or CIP terms. To determine the correct date of delivery hereafter specified, the Purchaser has taken into account the additional time that will be needed for international or national transit to the site or to another common place.

Schedule of Requirement Contraceptives Health / Population Welfare Department Khyber Pakhtunkhwa

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

#	Products	Quantity	No of shipments	First delivery	Second delivery	Total Delivery period	Shelf life minimum[6]	Place of delivery	Remarks
1	Male Latex Condoms		2	120 days (60%)	60 days (40%)	180 days (100%)	75%	CWH, Karachi	WHO Pre-qualified[7]products shall be quoted. Each batch to be supplied shall be delivered with WHO accredited lab test report.
2	IUD (Cu-T380A)		1	120 days		120 days	75%	CWH, Karachi	
3	Implant *(Double Rod)*								
4	Implant *(Single Rod)*								
5	COC *(cycles)*		2	90 days (60%)	30 days (40%)	120 days (100%)	75%	CWH, Karachi	Each batch of locally manufactured contraceptive to be tested from Central Drug Testing Laboratory, Karachi/DTL Khyber Pakhtunkhwa as per Drug Act standard testing policies. [8]
6	POP *(cycles)*								
7	ECP *(Pack of 2 tabs)*								
8	Injectable DMPA *with syringes (3 month)*		2	90 days (60%)	30 days (40%)	120 days (100%)	75%	CWH, Karachi	
9	Injectable *(2 month)*								

Mode of Penalty

Late delivery charges/penalty @ 0.067 % per day after 30 days after each installment delivery as per Schedule of Requirement Contraceptives

[6] Product shelf life upon delivery shall not be less than 75% of the product's documented shelf life
[7] Evaluation criteria (1) WHO prequalification certificate for international bidders / imported items
[8] Evaluation criteria (2) Affidavit of local manufacturer that the PA reserves the right to get maximum up to 5 batches/lots tested from WHO accredited labs for quality assurance from the total supplied batches against each item

Information about Technical Specifications - General

Technical specifications are one of the most important elements of procurement:

- They provide detailed information to bidders about the goods to be purchased.
- They are the benchmarks against which the purchaser will judge the technical responsiveness of bids.
- They form the basis for the contractual obligation of the supplier to the purchaser.
- They are the criteria against which the purchaser will determine the acceptability of specific goods prepared by the seller for shipment.

Technical specifications must be clear, accurate and complete; otherwise, the procurement will not be able to proceed on schedule and the entire procurement process may need to be cancelled:

- Questions raised by bidders can force the procuring entity to push back the deadline for bid submission to accommodate amendments to the bidding documents.
- A significant number of bidders may misunderstand the requirements and quote items that do not meet program needs, forcing the procuring entity to reject all bids and re-start the process.
- It may be impossible for the evaluation committee to correctly identify a winning bid, and if one is chosen for any other reason than what is specifically stated in the bidding documents, bidder protests may result, which can create delays in the procurement process.
- Goods that do not meet program needs may be delivered because the supplier is under no obligation to supply goods other than what is specifically described in the bidding documents.

Under any of the above scenarios, time and resources will be wasted: at a minimum, the delivery schedule will be delayed. Further up the consequence scale, needs will not be met, legal problems may ensue, mis-procurement may be declared and funding may be lost.

In addition to specifications that are clear, accurate and complete, public sector procurement requires that specifications be prepared in a way that will encourage maximum competition. They must be "product neutral". In other words, they must use generic terms, relative characteristics and performance requirements rather than brand names and superficial descriptions. If there is no way to avoid stating a brand name, it must be followed by "or equivalent". Non-functional requirements such as colour and exact dimensions must have strong justification and may not be used simply to eliminate all but a specific brand.

Specifications must be written in industry-standard vocabulary so there is no question about what is required. Contraceptives and pharmaceuticals can be described in scientific terms with reference to a specific pharmacopoeia. Medical devices can be described according to a system developed in the European Community which is used in the US and some other countries as well, the Global Medical Device Nomenclature (GMDN). The use of standard nomenclature eliminates misunderstanding and miscommunication due to variation in the use of terms (in English) by different countries and through translations from other (main) languages.

Specifications are not just about the physical product in terms of technical and performance characteristics, size, units and quantity, but should also include a description of:

- Intended use
- Packaging and marking
- Packing and shipping marks
- Regulatory requirements
- Standards and required certifications

- Quality assurance criteria including detailed tests required
- Acceptance criteria
- Detailed activities to be performed by the supplier
- Documentation

How to obtain appropriate specifications, and/or who should prepare them can be a challenge for the procurement unit. Considering the depth of knowledge and specialized information required for writing effective, unambiguous procurement specifications, it is a job best done by a person with specific technical expertise. Line Directors and end users are aware of their requirements from the standpoint of using a product, but they are not usually the best authority on how the product is put together. In addition, they may not be familiar with the scientific terms needed to accurately describe it.

The role of procurement staff in specification development includes gathering information, facilitating communication between technical personnel and end users, consulting with the technical expert, and placing the completed specification in the bidding documents. Actually writing specifications is not a job for procurement officers.

Specifications that have been developed in the past and preserved in a file or database for future use are very convenient; however, a technical expert should be asked to review them to make sure they accurately and completely reflect the current requirement before they are adopted for use in a procurement action.

The following checklist can be used as a guide in preparing or reviewing a contraceptive technical specification to ensure that all of the key components of a contraceptive specification have been included in the document.

Checklist of Elements for Inclusion in Specifications for Pharmaceuticals and Contraceptives

- **Description**: Generic name (INN); Type of product; Intended use
- **Formulation (drug content):** Pills & Injectable
- **Registration number**
- **Drug Manufacturing License Number**
- **Materials: Condoms & IUDs**
- **Presentation:** Dosage form; Dosage size
- **Filling Volume (as applicable)**
- **Identification (markings):** Marking/labeling of product
- **Primary Packaging:** Materials and description; Package layout/dimensions; Markings; Special labeling/logo (if desired)
- **Over packing (cartons):** Materials and description; Markings
- **Exterior Packing (for shipping):** Materials and description; Markings
- **Shelf Life:** In months or years; Stability/storage temperature; Months remaining upon receipt in-country
- **Printed Materials:** Language; Patient inserts; Physician inserts; Special instructions
- **Regulatory Requirements**
- **Quality Assurance Requirements:** Pharmacopoeia standard (if applicable)
- **Documentation:** Test data; Certificate of Analysis; Regulatory certificates
- **Quality Compliance Provisions:** Pre-shipment inspection (of physical attributes); Preshipment sampling and testing (for analysis of suspect products)

Technical Specifications and Ancillary Services

a). Product Specifications.

(Detailed technical specifications given below)

b). Labeling and Packing

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

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, expiry date, registration No., batch No., retail price, and Urdu version namely: name of drug, dosage and instructions, should also be written on the outer carton and on the most inner container in bold letters. All tablets shall be supplied in strip / blister pack (one side aluminum and other side PVC/PVD). Expiry date must be printed on each blister.

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 Drug Act, 1976 on judicial paper.

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 etc.

"KHYBER PAKHTUNKHWA GOVERNMENT PROPERTY"

"NOT FOR SALE"

iii. After signing of the Contract, the Supplier shall submit the samples of finished products in accordance with the above instructions for approval of the concerned Procuring Agency. The approved samples will be shared with the districts and all subsequent supplies must be in accordance with the approved samples.

d). Shelf life

i. The shelf life must be up to **85% for the locally manufactured contraceptives** and **75% for the imported contraceptives**.

ii. The lower limit of the shelf life must be up to **80% and 70% with imposition of 1% penalty** charges of actual shortfall in shelf life below prescribed limit for locally manufactured and imported contraceptives respectively.

e). Testing/Verification Procedures

i. For imported items, acceptable quality report from WHO prequalified lab for testing contraceptives is mandatory with each batch supplied[9].

ii. After delivery of contraceptives (Injections and oral pills) 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 may send samples from few batchs 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.

iii. 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.

f) 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. 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.

[9] 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

Technical Specification - Oral Contraceptive

Information for submission of samples

The sample oral contraceptives submitted by the Bidder in response to this Invitation for Bids must be exactly the same[10] as would be supplied if a contract were awarded to the Bidder. The packets containing the product need not have a printed logo as stipulated under Clause 1.12 of this specification; however, other information as stipulated under the aforementioned clause must be furnished. For sample submission only, this information (logo optional) may be printed on a sticker and affixed to the packets containing the product. The purchaser should replace italics with the actual requirements of the contraceptive to be procured.

1. Requirements

Oral contraceptive tablets in accordance with the following specifications:

- Twenty-eight (28)-day cycle package consisting of twenty-one (21) oral contraceptive norgestrel and ethinyl estradiol tablets and seven (7) ferrous fumarate tablets.
- Contraceptive tablets: 21
    - Each tablet shall contain 0.03 mg of ethinyl estradiol and 0.3 mg of norgestrel.
- Spacing tablets: 7
    - Each tablet shall contain 75 mg ferrous fumarate.

1.1 Product and Brand Names

Product name: ……

Brand names: …….

Registration Number: …….

1.2 Raw Materials

Oral contraceptives offered under this purchase description shall be produced from validated raw materials obtained from a licensed manufacturer or its authorized distributor.[11]

1.3 Registration Requirements

Oral contraceptives offered under this purchase description shall be currently registered in Pakistan and approved by the Ministry of Health under the Drugs Act, 1976.

1.4 Certificate of Registration Status in Country of Origin (in case of imported drugs)

Oral contraceptives 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,

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[10] *For example, same tablet shape, colour, weight, ingredients and identification imprint; same blister pack size, material, text and identification markings; same inner box size, material, text and identification markings.*

[11] *Because the raw materials that make up both active and inactive ingredients are of great importance for final product bioavailability and stability, current good manufacturing practices require that manufacturers validate vendors for all raw materials. A typical validation includes, but is not limited to, these areas:*

- *Manufacturing records and procedures for raw materials synthesis, processing, packing and storage.*
- *Quality control records and procedures for the raw materials, in-process and final product.*
- *Plant certification by local regulatory authorities (such as commerce, industry, health, labour, environment) as required.*
- *Certification of workers' training in current good manufacturing practices and safety protection.*
- *Records demonstrating raw materials with the required physical and chemical characteristics.*

the successful offeror(s) may be required to submit a "statement of licensing status of pharmaceutical product(s)" as provided under the World Health Organization (WHO) Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce.[12]

1.5 Compliance With Current Good Manufacturing Practices

The Supplier must be able to provide certification that the oral contraceptives are manufactured according to WHO current good manufacturing practices (cGMPs). Such certification can be found in the WHO Certification Scheme "Certificate of Pharmaceutical Product." Supplier also must be able to provide copies of its annual cGMP audit reports conducted by the local Drug Regulatory Authority.

1.6 WHO Certification—Movement in International Commerce

The Supplier must be able to provide documentation indicating that the manufacturer of the product has received confirmation from the Ministry of Health of the country of manufacture that the pharmaceutical meets the requirements in the WHO Certification Scheme.

1.7 Shape and Dimensions

Tablets shall be of the shape and dimensions of the Bidder's normal, standard commercial tablets which are available in the local market.

1.8 Colors

Contraceptive and ferrous fumarate (or inert, if applicable) tablets shall be similar to Bidder's normal, standard commercial tablets.

1.9 Tablet Markings

Each tablet shall bear the identifying imprint of its manufacturer.

1.10 Packaging

1.10.1 Monthly Cycle Presentation

Each individual tablet shall be enclosed in a transparent blister pack of thermoformed polymer, with a minimum thickness of 0.1905 mm (.0075 inch) backed with aluminum foil, minimum thickness 0.0178 mm (0.0007 inch). Variations must be proven scientifically comparable by means of stability data.

The size of the package shall not be less than 57.15 mm (2.25 inches) x 82.55 mm (3.25 inches). Thicker polymer or foil or the addition of a card to either the front or the back of the package (in addition to the minimum polymer or foil) is acceptable.

1.10.2 Mounting

Tablets shall be mounted on four (4) rows of seven (7) tablets per row. Contraceptive tablets shall precede the ferrous fumarate tablets (or inert tablets, if applicable).

1.11 Identification Markings on Individual Blister Packs

Each individual blister pack shall have the following information:

[12] *Available at: http://www.who.int/medicines/areas/quality_safety/regulation_legislation/certification/en/index.html.*

- Product/brand name
- Lot/batch number
- Expiration date (day, month and year)
- Date of manufacture
- Manufacturer's name and address
- Arrow indicating sequence of tablets
- Contents and quantity, including tablet formulation (amounts of active ingredients per tablet)
- Drug registration number (if applicable)
- Family planning logo (if applicable)
- Drug Manufacturing License Number
- Product use and storage instructions (accompanying the blister pack).

1.11.1 Printing and Layout

On the front of each monthly cycle above the first row of tablets and in the left-hand corner, the trade or brand name of the product shall be printed in full. In parentheses, in reduced lettering (smallest type no less than 1 mm high) and below the product or brand name, shall be printed "Family Planning Pills." Sequence of administration shall be clearly indicated by an arrow/line pathway on the unit.

The day, month and year of expiration shall be shown in the following format DD/MM/YY. The lot/control number shall be shown in English numerals. Debossing is acceptable for these numbers.

The tablet formulation and a "copy control code" (evidence that artwork/packaging has been approved by all parties) shall be printed on the individual packet and may be printed on the reverse side (smallest type no less than 1 mm high).

1.11.2 Colour

Background colour shall be the natural colour of the aluminum foil on the face, with a dark blue (PMS Blue 301) stripe across the top and the "Blue Lady" symbol depicted to the right but within the blue stripe. The reverse of the individual packet will not be inked except for necessary printing.

1.12 Workmanship

Products and packaging shall be free of defects that impair their serviceability, affect their durability, or detract from their appearance.

1.13 Lots Per Order

The Supplier shall fill the order using the fewest number of manufacturing lots possible.

1.14 Shelf Life

The shelf life of the product provided under this solicitation shall be five (5) years from the date of manufacture when stored under tropical conditions such as those prevailing in the local environment. The Supplier shall be able to provide to the satisfaction of the registration/national quality control authorities the manufacturer's stability test data substantiating this five (5) year shelf life at ambient temperatures at or greater than 32 degrees Celsius and at a relative humidity of 85% in the proposed blister package.

At the time of inspection or acceptance for delivery to the country of destination, no more than nine

(9) months shall have expired since the date of manufacture shown on the batch release or Certificate of Analysis.

1.16 Test Data

Chemical and physical test data for raw materials, components in-process and finished product testing must be on record for each lot manufactured and must be available to Purchaser's representatives when requested.

2. Quality Assurance Provisions

2.1 Compliance

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

2.2 Documentation

2.2.1 The Supplier shall provide evidence[13] 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.

2.2.2 The Supplier shall provide a copy of the manufacturing record and procedures to the Purchaser for each lot intended for supply.

2.2.3 The Supplier shall provide a copy of the Certificate of Analysis to the Purchaser for each lot intended for supply.

2.2.4 The Supplier shall provide to the Purchaser a copy of the approval of each component for each lot intended for supply.

2.3 Inspection by the Purchaser

The Purchaser reserves the right to perform or cause to be performed any of the inspections and tests set forth in the Technical Specifications and Special Conditions of Contract to ensure that the goods conform to prescribed requirements. The Purchaser reserves the right, and/or may assign the right to a representative, to enter and inspect the production facility prior to supply of the goods and to draw samples from the Supplier's factory and/ or warehouse for test analysis. Except as otherwise specified in the Contract or purchase order, prior to supply, the Purchaser 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.[14]

The Purchaser may have some or all of the tests specified in the Technical Specifications (Dossier) of the Contract performed by a laboratory suitably equipped and qualified to conduct quality assurance tests on pharmaceutical products according to the Pharmacopoeia specification.

2.4 Sampling Procedures

The Purchaser, or the Purchaser's representative, shall select the required samples from the lot

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[13] *Evidence includes quality control and manufacturing records, in-process control records and final product Certificate of Analysis.*

[14] *Depending on the tests required, sampling may be conducted according to the standards of the InternationalOrganization for Standardization (ISO 2859: Inspection by Attributes) (included as Appendix IVI.H), the report of the WHO Expert Committee on Specifications for Pharmaceutical Preparations (included as Appendix IVI.I), or as dictated by local or international pharmacopoeia. Following recognized sampling procedures helps to ensure that the products tested arerepresentative of the whole.*

according to 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.

The normal, tightened and reduced inspection provisions of ISO 2859 (Inspection by Attributes) may be used for visual inspection. Sampling for analytical testing shall be done in accordance with pharmacopoeial requirements.

All sampled boxes and supply cartons shall be so marked and shall include the date and initials of the sampler.

2.5 Sample Retention

The Supplier shall retain a sample of ten (10) cycles, or the equivalent required to perform three (3) complete chemical assays, from each lot shipped, for a period of one (1) year after the printed expiration date.

3. Packing

3.1 Inner Boxes

3.1.1 Products sealed in individual packets as specified in Section 1.11 shall be packed in inner boxes of one hundred (100) cycles.[15]

Inner boxes shall be made of light fiberboard (white) of a size sufficient to contain the specified number of cycles. The overall dimensions should be such that the product does not get damaged during transportation and storage.

3.1.2 For inner boxes, the Bidder shall fill in the blanks provided below:

Each inner box will contain one hundred (100) cycles. The overall dimensions of a box will be cm x cm x cm.

3.2 Exterior Shipping Cartons

3.2.1 Product and printed materials, packaged and packed as specified above, shall be contained in triple-wall corrugated fiberboard cartons made from weather-resistant fiberboard with a bursting test strength of not less than 1,900 kPa. The carton flaps shall be secured with water-resistant adhesive applied to not less than 75% of the area of contact between the flaps or with 75 mm-wide water-resistant tape applied to the full length of the center seams and extending over the ends not less than 75 mm[16]. Plastic strapping shall be placed around the carton, with a minimum of two crossing bands. Cartons exceeding 760 mm (30 inches) in length shall have additional bands placed around the carton.

3.2.2 The Bidder shall fill in the following blanks:

The exterior shipping carton will contain inner boxes. The overall dimensions of a carton will be cm x cm x cm, and the gross weight of one shipping carton will be kg.

A standard 6.096-meter (20-foot) container will accommodate exterior shipping cartons.

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[15] *Sometimes oral contraceptives are packaged to contain three (3) cycles per inner box. If this is the preferred configuration, a three (3)-cycle-per-box packaging description should be detailed in the specification.*

[16] *The use of additional tape along the joint of the outer lids and around the top and bottom corners will greatly increase each carton's resistance to damage during shipment and storage. Tape can be made of plastic film, Kraft paper, or fabric, either plain or reinforced with plastic threads.*

3.3 Markings

3.3.1 Inner Boxes

The inner boxes shall be marked with the following information in a clearly legible manner that is acceptable to the Purchaser[17]:

- Product/brand name
- Drug Manufacturing License Number
- Lot/batch number
- Expiration date (day, month and year)
- Date of manufacture
- Manufacturer's name and address
- Contents and quantity
- Drug registration numbers (if applicable)
- Instructions for storage and handing

3.3.2 Exterior Supply Cartons

The following information shall be stenciled or labeled on the exterior supply cartons on two opposing sides in bold letters at least ……..mm high with waterproof ink in a clearly legible manner that is acceptable to the Purchaser.[18]

Regulatory information (on two opposing sides of carton)

- Product/brand name
- Drug Manufacturing License Number
- Lot/batch number
- Expiration date (day, month and year)
- Date of manufacture
- Manufacturer's name and address
- Contents and quantity
- Drug registration numbers (if applicable)
- Instructions and symbols for storage and handling, such as KEEP DRY or DO NOT FREEZE

Customs and shipping information (on two opposing sides of carton)

- Made in
- Supplier's name and address (if different from manufacturer)
- Consignee's address in full
- Gross weight of each carton (in kg)
- Port of entry
- Contract number
- Quantity of goods

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[17] *The smallest type shall be no less than 1 mm high, unless otherwise specified by the commercial laws of the country of importation.*

[18] *The smallest type shall be no less than 10 mm high, unless otherwise specified by the commercial laws of the country of importation.*

- Carton of

3.4 Printed Materials—Product Information Sheets

3.4.1 Consumer information and directions for use shall be printed in English and/or in and provided as package inserts, one copy for each consumer unit. All copies are to be accumulated, fastened together and included in each exterior supply carton.

3.4.2 Information for physicians' use shall be printed in English and/or in Urdu. Two copies of such information shall be provided for each one thousand two hundred (1,200) monthly cycles and shall be placed in each exterior supply carton.

Inspection Sampling and Testing—Oral Contraceptives

Prior to shipment, the Purchaser or its appointed representative has the right to sample and inspect each consignment of oral contraceptives at the factory or Supplier's warehouse in accordance with ISO 2859 Inspection by Attributes (or WHO specifications) and Technical Specification of this Contract.

1.1 Packaging, Packing and Markings

a. One hundred percent (100%) of the exterior supply cartons will be examined for:
   - General physical characteristics and condition.
   - Markings per Technical Specification
b. A representative sample of the inner boxes and individual packages will be drawn from the exterior supply cartons at General Inspection Level II, or, at the discretion of the Purchaser, General Inspection Level III, Single Sampling Plan for Normal Inspection.
c. The sample will be examined for:
   - General physical characteristics per Technical Specification, Section
   - Markings per Technical Specification, Section
d. Inspection criteria and classification of defects shall follow the inspection guidelines outlined in Section 1.4 below. For critical defects, the acceptable quality limit (AQL) shall be 0%; for major defects, the AQL shall be 1%; for minor defects, the AQL shall be 4%.

1.2 Tablet

At the discretion of the Purchaser, part of the selected sample may be sent to a qualified government drug testing laboratory for physical and chemical testing as follows.

Pharmacopoeial tests:

- Identification
- Assay of active ingredient(s)
- Content uniformity
- Disintegration and/or dissolution
- Uniformity of mass (not required if content uniformity test performed)

Non-pharmacopoeial tests:

- Package seal integrity test.[19]

[19] *Immerse package in 0.05 percent methylene blue solution under 15 vacuum gauge for two minutes.Observe for leakage. AQL 2.5%.*

A Certificate of Analysis for production lot(s) shall be made available to the inspector and/ or Purchaser upon request. The certificate shall state all tests performed, their specifications, and actual test results obtained. All pharmacopoeial test results shall meet applicable pharmacopoeial limits.

1.3 Resolution of Defects

a. Packaging, Packing, and Markings
   - Defects in exterior shipping carton markings must be corrected by the Supplier prior to supply.
   - All goods from corresponding production lots with inspection lot defect in excess of the AQLs listed in Section 1.4 of this specification must be corrected and re-inspected at Supplier's expense or rejected.

b. Tablet
   - Any deviation from the manufacturer's Certificate of Analysis, product specifications,

     or

     relevant pharmacopoeial limits shall result in rejection of goods from the entire production lot.

Technical Specifications - Injectable Contraceptives

Information for Submission of Samples

The sample injectable contraceptives submitted by the Bidder in response to this Invitation for Bids must be exactly the same as would be supplied if a contract were awarded to the Bidder.[20] The vial or ampoule containing the product need not have a printed logo; however, other information as stipulated under Clause 1.11 of this specification must be furnished. For sample submission only, this information (logo optional) may be printed on a sticker and affixed to the vials or ampoules containing the product. The purchaser should replace italics with the actual requirements of the contraceptive to be procured.

1. Requirements

Injectable contraceptives in accordance with the following specifications:

- Long-acting progestin in sterile aqueous suspension for intramuscular injection once every three (3) months.
- Each 1-ml vial or ampoule should contain a minimum of 1.1 ml of sterile aqueous suspension containing 150 mg/ml medroxy progesterone acetate.

1.1 Product and Brand Names

Product name: ……

Brand names: ……..

Registration Number: ……..

Drug Manufacturing License Number: ……..

1.2 Raw Materials

Injectable contraceptives offered under this purchase description shall be produced from validated raw materials obtained from a licensed manufacturer or its authorized distributor.[21]

1.3 Primary Packaging Requirements

Injectable contraceptives offered under this purchase description shall be packaged in vials or ampoules that meet quality standards as specified in ISO 8362-1. Closures for injection vials shall meet quality standards as specified in ISO 8362-2.

1.4 Registration Requirements

Injectable contraceptives offered under this purchase description shall be currently registered in Pakistan and approved by the Ministry of Health under the Drugs control Act 1976. (local regulatory authority).

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[20] *For example, vials or ampoules must be of the same glass type, closure type, colour, size, text and identification markings; contents must have same ingredients, colour and weight; same inner box size, material, text and identification markings.*

[21] *Because the raw materials that make up both active and inactive ingredients are of great importance for final product bioavailability and stability, current good manufacturing practices require that manufacturers validate vendors for all raw materials. A typical validation includes, but is not limited to, these areas:*

- *Manufacturing records and procedures for raw materials synthesis, processing, packing and storage.*
- *Quality control records and procedures for the raw materials, in-process and final product.*
- *Plant certification by local regulatory authorities (such as commerce, industry, health, labour, environment) as required.*
- *Certification of workers' training in current good manufacturing practices and safety protection.*
- *Records demonstrating raw materials with the required physical and chemical characteristics.*

1.5 Certificate of Registration Status in Country of Origin (in case of imported drugs)

Injectable contraceptives 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 product(s)" as provided under the World Health Organization (WHO) Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce.[22]

1.6 Compliance with Current Good Manufacturing Practices

The Supplier must be able to provide certification that the injectable contraceptives are manufactured according to WHO current good manufacturing practices (cGMPs). Such certification can be found in the WHO Certification Scheme "Certificate of Pharmaceutical Product". Supplier also must be able to provide copies of its annual cGMP audit reports conducted by the local Drug Regulatory Authority.

1.7 WHO Certification—Movement in International Commerce

The Supplier must be able to provide documentation indicating that the manufacturer of the product has received confirmation from the Ministry of Health of the country of manufacture that the pharmaceutical meets the requirements in the WHO Certification Scheme.

1.8 Appearance

Injectable contraceptives shall appear as an aqueous white suspension contained in 1-ml or 10-ml glass vials or 1-ml glass ampoules.

1.9 Filling Volume

Each 1-ml glass vial or ampoule shall contain a minimum of 1.1 ml of sterile aqueous suspension.

Each 10-ml glass vial shall contain a minimum of 10.5 ml of sterile aqueous suspension.

1.10 Identification Markings on Individual Vials or Ampoules

Each individual vial or ampoule shall have the following information:

- Product/brand name
- Lot/batch number
- Expiration date (day, month and year)
- Date of manufacture
- Manufacturer's name and address
- Presentation (e.g., sterile aqueous suspension)
- Formulation (amounts of active ingredients per vial or ampoule)
- Drug registration number (if applicable)
- Family planning logo (if applicable)

If space allows, the following information shall also appear on each individual vial or ampoule:

- Recommended storage conditions.
- Drug Manufacturing License Number.

1.11 Workmanship

[22] *Available at: http://www.who.int/medicines/areas/quality_safety/regulation_legislation/certification/en/index.html.*

Products and packaging shall be free of defects that impair their serviceability, affect their durability or detract from their appearance.

1.12 Lots Per Order

The Supplier shall fill the order using the fewest number of manufacturing lots possible.

1.13 Shelf Life

The shelf life of the product provided under this solicitation shall be at least three (3) years from the date of manufacture when stored under tropical conditions such as those prevailing in the local environment. The Supplier shall be able to provide to the satisfaction of the registration/national quality control authorities the manufacturer's stability test data substantiating this three (3) year shelf life at ambient temperatures at or greater than 32 degrees Celsius and at a relative humidity of 85% in the proposed vial or ampoule.

At the time of inspection or acceptance for delivery to the country of destination, no more than nine (9) months shall have expired since the date of manufacture shown on the batch release or Certificate of Analysis.

1.14 Test Data

Chemical, physical and microbiological test data for raw materials, components in-process and finished product testing must be on record for each lot manufactured and must be available to Purchaser's representatives when requested.

2. Quality Assurance Provisions

2.1 Compliance

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

2.2 Documentation

2.2.1 The Supplier shall provide evidence[23] 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.

2.2.2 The Supplier shall provide a copy of the manufacturing record and procedures to the Purchaser for each lot intended for supply.

2.2.3 The Supplier shall provide a copy of the Certificate of Analysis to the Purchaser for each lot intended for supply.

2.2.4 The Supplier shall provide to the Purchaser a copy of the approval of each component for each lot intended for supply.

2.3 Inspection by the Purchaser

The Purchaser reserves the right to perform or cause to be performed any of the inspections and tests set forth in the Technical Specifications and Special Conditions of Contract to ensure that the goods conform to prescribed requirements. The Purchaser reserves the right, and/or may assign the right to a representative, to enter and inspect the production facility prior to supply of the

[23] *Evidence includes quality control and manufacturing records, in-process control records and final product Certificate of Analysis.*

goods and to draw samples from the Supplier's factory and/or warehouse for test analysis. Except as otherwise specified in the Contract or purchase order, prior to shipment, the Purchaser 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.[24]

The Purchaser may have some or all of the tests specified in the Technical Specifications of the Contract performed by a laboratory suitably equipped and qualified to conduct quality assurance tests on pharmaceutical products according to Pharmacopoeia specifications.

2.4 Sampling Procedures

The Purchaser or the Purchaser's representative shall select the required samples from the lot according to 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.

The normal, tightened and reduced inspection provisions of ISO 2859 (Inspection by Attributes) may be used for visual inspection. Sampling for analytical testing shall be done in accordance with pharmacopoeial requirements.

All sampled boxes and supply cartons shall be so marked and shall include the date and initials of the sampler.

2.5 Sample Retention

The Supplier shall retain a sample of ten (10) vials or ampoules, or the equivalent required to perform three (3) complete chemical assays, from each lot shipped, for a period of one (1) year after the printed expiration date.

3. Packing

3.1 Inner Boxes

3.1.1 One hundred (100) individual glass vials or ampoules will be contained in sturdy white cardboard boxes outfitted with individual segments for protecting and separating each vial or ampoule.

Inner boxes shall be made of sturdy white cardboard of a size sufficient to contain the specified number of vials or ampoules. The overall dimensions should be such that the product does not get damaged during transportation and storage.

3.1.2 For inner boxes, the Bidder shall fill in the blanks provided below:

Each inner box will contain one hundred (100) units. The overall dimensions of a box will be cm x cm x cm.

3.2 Exterior Shipping Cartons

3.2.1 Product and printed materials, packaged and packed as specified above, shall be contained in triple-wall corrugated fiberboard cartons made from weather-resistant fiberboard with a bursting test strength of not less than 1,900 kPa. The carton flaps shall be secured with water resistant adhesive applied to not less than 75% of the area of contact between the flaps or with 75

[24] *Depending on the tests required, sampling may be conducted according to the standards of the International Organization for Standardization (ISO 2859: Inspection by Attributes) (included as Appendix IVI.H), the report of the WHO Expert Committee on Specifications for Pharmaceutical Preparations (included as Appendix IVI.I), or as dictated by local or internationalpharmacopoeia. Following recognized sampling procedures helps to ensure that the products tested are representative of the whole.*

mm-wide water-resistant tape applied to the full length of the center seams and extending over the ends not less than 75 mm[25]. Plastic strapping shall be placed around the carton, with a minimum of two crossing bands. Cartons exceeding 760 mm (30 inches) in length shall have additional bands placed around the carton.

3.2.2 Additional cushioning shall be provided as needed to protect the vials or ampoules from breakage during transit and handling.

3.2.3 The Bidder shall fill in the following blanks:

The exterior shipping carton will contain inner boxes. The overall dimensions of a carton will be cm x cm x cm, and the gross weight of one shipping carton will be kg.

A standard 6.096-meter (20-foot) container will accommodate exterior shipping cartons.

3.3 Markings

3.3.1 Inner Boxes

The inner boxes shall be marked with the following information in a clearly legible manner which is acceptable to the Purchaser[26]:

- Product/brand name
- Drug manufacturing License number
- Lot/batch number
- Expiration date (day, month and year)
- Date of manufacture
- Manufacturer's name and address
- Contents and quantity
- Drug registration number (if applicable)
- Instructions for storage and handing
- Formulation and presentation

3.3.2 Exterior Shipping Cartons

The following information shall be stenciled or labeled on the exterior shipping cartons on two opposing sides in bold letters at least mm high with waterproof ink in a clearly legible manner that is acceptable to the Purchaser.[27]

Regulatory information (on two opposing sides of carton)

- Product/brand name
- Drug manufacturing License Number
- Lot/batch number
- Expiration date (day, month and year)
- Date of manufacture

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[25] *The use of additional tape along the joint of the outer lids and around the top and bottom corners will greatly increase each carton's resistance to damage during shipment and storage. Tape can be made of plastic film, Kraft paper, or fabric, either plain or reinforced with plastic threads.*

[26] *The smallest type shall be no less than 1 mm high, unless otherwise specified by the commercial laws of the country of importation.*

[27] *The smallest type shall be no less than 10 mm high, unless otherwise specified by the commercial laws of the country of importation.*

- Manufacturer's name and address
- Contents and quantity
- Drug registration numbers (if applicable)
- Instructions and symbols for storage and handling, such as KEEP DRY or DO NOT FREEZE.

Customs and shipping information (on two opposing sides of carton)

- Made in...
- Supplier's name and address (if different from manufacturer)
- Consignee's address in full
- Gross weight of each carton (in kg)
- Port of entry
- Contract number
- Quantity of goods
- Carton of

3.4 Printed Materials—Product Information Sheets

Twenty (20) patient information sheets and one (1) prescribing information sheet, printed in English and/or in, shall be included in each intermediate container.

Inspection Sampling and Testing—Injectable Contraceptives

Prior to shipment, the Purchaser or its appointed representative has the right to sample and inspect each consignment of injectable contraceptives at the factory or Supplier's warehouse in accordance with ISO 2859 Inspection by Attributes (or WHO specifications) and Technical Specification of this Contract.

1.1 Packaging, Packing and Markings

a. One hundred percent (100%) of the exterior shipping cartons will be examined for:
   - General physical characteristics and condition
   - Markings per Technical Specification ...

b. A representative sample of the inner boxes and individual vials or ampoules will be drawn from the exterior shipping cartons at General Inspection Level II, or, at the discretion of the Purchaser, General Inspection Level III, Single Sampling Plan for Normal Inspection.

The sample will be examined for:

- General physical characteristics per Technical Specification Section
- Markings per Technical Specification, Section c. Inspection criteria and classification of defects shall follow the inspection guidelines outlined in Section 1.4 below. For critical defects, the acceptable quality limit (AQL) shall be 0%; for major defects, the AQL shall be 1%; for minor defects, the AQL shall be 4%.

1.2 Injectable

At the discretion of the Purchaser, part of the selected sample may be sent to a qualified government drug testing laboratory for physical, chemical or microbiological testing as follows.

Pharmacopoeial tests

- Active ingredient(s) identification and assay

- Appearance (colour, turbidity, visible particles)
- Filling volume
- pH
- Preservative identification
- Pyrogens
- Sterility

Non-pharmacopoeial tests

- Package seal integrity test
- Particle size (for suspensions only)

A Certificate of Analysis for production lot(s) represented by test samples shall be made available to the inspector and/or Purchaser upon request. The certificate shall state all tests performed, their specifications and actual test results obtained. All pharmacopoeial test results shall meet applicable pharmacopoeial limits.

1.3 Resolution of Defects

a. Packaging, Packing and Markings
   - Defects in exterior shipping carton markings must be corrected by the Supplier prior to shipment.
   - All goods from corresponding production lots with inspection lot defect in excess of the AQLs listed in Section 1.4 of this specification must be corrected and re-inspected at Supplier's expense or rejected.

b. Injectable
   - Any deviation from the manufacturer's Certificate of Analysis, product specifications or relevant pharmacopoeial limits shall result in rejection of goods from the entire production lot.

Technical Specification - Male Latex Condom[28]

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

General Requirements (to be verified during prequalification)	
Materials	
General Requirements (to be verified during prequalification)	The condoms shall be made of natural rubber latex.
	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.
Bioburden levels	Condoms are not sterile devices, but nevertheless manufacturers should take steps to minimize the risk of contamination of the products with micro-organisms.
Biocompatibility	Biocompatibility assessments shall be conducted in accordance with ***ISO 10993–1.*** Specifically, tests shall be conducted for cytotoxicity according to *ISO 10993–5* and for irritation and sensitization according to ***ISO 10993–10.*** Manufacturers should choose accredited laboratories for these tests and the results should be interpreted by an accredited toxicologist or other suitably qualified expert. Expert reports should be available for review.
	It is recommended **that bioburden levels be determined periodically,** e.g. at least quarterly, by *Manufacturers and/or the Procuring Agency are advised to confirm local requirements for safety testing with appropriate regulatory authorities in the country of intended use. Condoms are tested according to ISO 10993*
nitrosamines	***It is recommended that manufacturers take steps to minimize the formation of nitrosamines.*** This can be achieved by ensuring that condoms are adequately leached and washed, by using minimum amounts of accelerators and by choosing accelerators, such as zinc dibutyldithiocarbamate, that have a preferred safety profile[2].
water-extractable protein levels	***It is recommended*** **that manufacturers determine the water-extractable levels of proteins in their products.**
	Powders (e.g. cornstarch, magnesium and calcium carbonates) should be used to prevent the condoms from sticking together during manufacture and to allow them to unroll easily.
	The recommended levels for soluble protein, as determined by the modified Lowry method, should be less than **200 µg/g.** Manufacturers should take steps not to exceed this level and should monitor production periodically.
	Manufacturers may use other dusting powders with the agreement of the Procuring Agency. In such cases the Procuring Agency may require the manufacturer to justify the choice of dusting powder.
	There is no specific standard for determining the protein levels in condoms. The methods described in *ISO 12243, EN 455–3* and *ASTM D5172* for determining the protein levels in medical gloves can be modified for condoms[1].
shelf-life and stability	Documentation recording protein levels should be available for review.
Shelf-life	Condoms shall comply with the performance requirements of this *WHO/UNFPA Specification* through- out the stated shelf-life of the condom.
	The manufacturer shall determine the shelf-life based on the outcome of stability studies and measured from the date of manufacture. *The date of manufacture is the date that the condoms were dipped.*

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 of 20 °C to 30 °C.

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[5].
sampling	Shelf-life shall be determined on condoms that have been stored for the maximum period of time between dipping and rolling that is permitted in the standard operating procedures of the manufacturer.
	Sample condoms from three manufacturing LOTS in accordance with Annex B of *ISO 4074.*
conditioning	Condition condoms at (50 ± 2) °C for 120 days or 180 days in accordance with the relevant annex of *ISO 4074.*
conditioning	Condition condoms at (30 $^{+5}$) °C in accordance with the relevant annex of *ISO 4074.*
testing requirement	Assess compliance with the requirements for bursting properties, freedom from holes and package integ- rity specified in the relevant clauses of *ISO 4074* at least annually for the full shelf-life of the product.
	All three LOTS of condoms shall remain in compliance with the requirements for bursting properties, freedom from holes and package integrity specified in the relevant clauses of *ISO 4074* for the duration of the stability study.

[28] 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

testing requirement	Assess compliance with the requirements for bursting properties, freedom from holes and package integrity specified in the relevant clauses of *ISO 4074*. If all three LOTS of condoms remain in compliance with the requirements for bursting properties, free- dom from holes and package integrity specified in the relevant clauses of *ISO 4074* for a period of **120 days** at (50 ± 2) °C, *a provisional shelf-life of **three years** may be assigned.* If all three LOTS of condoms remain in compliance with the requirements for bursting properties, free- dom from holes and package integrity specified in the relevant clauses of *ISO 4074* for a period of **180 days** at (50 ± 2) °C, *a provisional shelf-life of **five years** may be assigned.*
Minimum stability requirements	Condoms shall comply with the minimum stability requirements defined in the relevant clause of *ISO 4074*. Condoms meeting these minimum stability requirements can be assumed to have a provisional shelf-life of two years.
sampling	Three LOTS sampled in accordance with *ISO 2859–1* and Annex B of *ISO 4074*.
conditioning	Incubate samples in their individual sealed containers according to the relevant annex of *ISO 4074:* • One set for 168 ± 2 hours at (70 ± 2) °C, and another set for (90 ± 1) days at (50 ± 2) °C. • At the end of the incubation periods, withdraw the condoms and test for airburst properties, freedom from holes and package seal. • The incubation period at (50 ± 2) °C can be extended to 120 or 180 days in order to estimate a provisional shelf-life by accelerated ageing, in which case testing at 90 days is not necessary.
testing 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 *ISO 4074*.

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 *ISO 2859–1* General Inspection Level I. For prequalification testing at least Code Letter M as specified in Annex B of *ISO 4074* shall be used.
testing	In accordance with test method in the relevant annex of *ISO 4074* and the relevant clause in *ISO 4074*.

requirement	**Minimum bursting requirements as listed below: AQL 1.5** **Volume:** 16.0 dm^3 for condoms with widths less than 50.0 mm 18.0 dm^3 for condoms with widths from 50.0 mm up to 55.5 mm 22.0 dm^3 for condoms with widths greater than or equal to 56.0 mm **Pressure:** 1.0 kPa (for all widths)
Bursting volume and pressure after oven conditioning (optional: see Annex I[6])	
sampling	In accordance with *ISO 2859–1* General Inspection Level I. For prequalification testing at least Code Letter M as specified in Annex B of *ISO 4074* shall be used.
testing	Condition the samples in accordance with the relevant annex of *ISO 4074* for (168 ± 2) hours at 70 °C. Remove from oven and keep the packages at (25 ± 5) °C until tested. Within 96 hours but no sooner than 12 hours after removal from the oven, determine the bursting volume and pressure in accordance with the test method in the relevant annex of *ISO 4074* and the relevant clause in *ISO 4074*.
requirement	**Minimum bursting requirements as listed below: AQL 1.5** **Volume:** 16.0 dm^3 for condoms with widths less than 50.0 mm 18.0 dm^3 for condoms with widths from 50.0 mm up to 55.5 mm 22.0 dm^3 for condoms with widths greater than or equal to 56.0 mm **Pressure:** 1.0 kPa (for all widths) The width is defined as the mean lay-flat width of 13 condoms measured in accordance with the relevant annex of *ISO 4074* at a point (75 ± 5) mm from the closed end, rounded to the nearest 0.5 mm.
Freedom from holes and visible defects	
sampling	*ISO 2859–1* General Inspection Level I, but at least Code Letter M. For prequalification testing at least Code Letter N as specified in Annex B of *ISO 4074* shall be used.
testing	In accordance with the relevant annex of *ISO 4074*.
requirement	In accordance with test method in the relevant annex of *ISO 4074*. Freedom from holes: **AQL 0.25** Critical visible defects: **AQL 0.4** Non-critical visible defects: **AQL 2.5** *ISO 4074* describes a limited number of critical visible defects. WHO specifies an extended list of critical visible defects and a list of non-critical visible defects in Chapter 3, Clauses 2.1 and 2.2. **exact definitions of critical and non-critical defects should be reviewed and agreed upon during the contractual process.**
Package seal integrity	

sampling	*ISO 2859–1* Inspection Level S-3.
testing	In accordance with the package integrity test method in the relevant annex of *ISO 4074*.
requirement	**AQL 2.5**

5 As described in *ISO 4074.*

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 Agency 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 program 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	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. Condoms may be of any shape consistent with normal commercial practice and client requirements. *If the condom is not parallel-sided and smooth, attach a dimensioned drawing with detailed description, and check here:*
Integral bead	
Verify by visual inspection	The open end of the condom shall have a rolled ring of latex, called an integral bead.
Colour	
Width	
sampling	In accordance with *ISO 2859–1* Inspection Level S-2.

Verify by visual inspection	Condoms can be translucent or coloured. **Pigments used with coloured condoms shall be suitable for use in medical devices.** If a pigment is required, indicate the colour here and provide full details of the pigment, including a Material Safety Data Sheet (MSDS).
odour, fragrance and flavour	
Verify by visual inspection and smell	The condoms shall not give off an unpleasant odour when the package is opened at any time after manufacture and for the shelf-life of the product. (Condoms have a characteristic odour of rubber, which tends to dissipate quickly once the package is opened. A mild odour that dissipates quickly is acceptable.) It is suggested that appropriate reference samples be retained by the testing laboratory to help resolve disputes over odour. It is recommended that the retained samples be kept for the duration of the shelf- life of the condom. Procuring Agencys 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. 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). 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.
testing	In accordance with the test method in the relevant annex of *ISO 4074*.
requirement	Standard widths within the public sector are 49 mm and 53 mm, with a tolerance of ± 2 mm. **AQL 1.0** 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. Indicate the width here:
Length	
sampling	In accordance with *ISO 2859–1* Inspection Level S-2.
testing	In accordance with the test method in the relevant annex of *ISO 4074*.
requirement	A minimum of 165 mm for condoms with widths less than 50.0 mm. A minimum of 180 mm for condoms with widths from 50.0 mm up to 55.5 mm. A minimum of 190 mm for condoms with widths equal to or greater than 56.0 mm. **AQL 1.0** Length may be specified based on the best available data on the target population. Indicate the length here: The width is defined as the mean lay-flat width of 13 condoms measured in accordance with the relevant annex of *ISO 4074* at a point (35 ± 15) mm from the open end, rounded to the nearest 0.5 mm.
thickness	
sampling	In accordance with *ISO 2859–1* Inspection Level S-2.

testing	In accordance with the test method in the relevant annex of *ISO 4074*.
requirement	The thickness measurements are taken at three points: 30 ± 5 mm from the open end, 30 ± 5 mm from the closed end (excluding the reservoir tip), and at the mid-distance between those two points. 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. 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. **AQL 1.0** The mean single-wall thickness (calculated from the three individual measurements) for each condom shall be 0.065 + 0.015 mm – 0.020 mm. *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.
Quantity of lubricant including powder	
sampling	*In accordance with ISO 2859–1 Inspection Level S-2.*
testing	*In accordance with the test method in the relevant annex of ISO 4074.*
requirement	*The condom shall be lubricated with a quantity of silicone fluid having a viscosity between 200 and 350 centistokes.* *Other lubricants such as glycols and water-based lubricants may be used. Oil-based lubricants* ***should NOT*** *be used.* *If an alternative lubricant is required, specify the type here and provide full details of the lubricant including a Material Safety Data Sheet (MSDS).* *The quantity of lubricant, including powder, in the package should be (550 ± 150) mg.* ***AQL 4.0*** *If user preferences indicate that it is desirable, lower lubricant levels may be used, but the minimum recommended quantity is 250 mg.* *If the lubricant quantity is less than (550 ± 150) mg, indicate here:*
Individual package materials and markings	
sampling	*In accordance with ISO 2859 Inspection Level S-3.*
testing	*The sample of condom packages is visually inspected to verify the required aspects of package quality.*
requirement	*The colour, print design and identification markings, including Pantone references and font sizes, shall be as specified by the buyer and annexed to this specification.* *The individual package shall have the following markings:* • *manufacturer's name;* • *LOT number or LOT identification code (printed at the time of packaging, not pre-printed);* • *expiry date: month and year labeled expiry date;* • *date in a language to be specified by the Procuring Agency.* *Manufacturing date: Month-and-year manufacturing date can be added if required by Procuring Agency.* *AQL 2.5*

Verified by visual inspection	*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 let and visible light.*
Verified by supplier's data or independent test	*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.*
Alternate package materials	*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.* 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. In addition, the following shall apply: • There shall be no evidence of leakage. • The outside surface of the package shall be clean. • There shall be no separation of the layers of laminate. • 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. • The package must be easy to open without damaging the condom.

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	
consumer packs	No consumer packs are included in the *WHO/UNFPA Specification.* If required, the full design of the consumer pack should be specified in accordance with the requirements of the program.
inner boxes	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. The inner boxes will be marked in a legible manner to describe the contents and to facilitate identification in case of subsequent query. **the following information shall be included in the inner box marking:** • LOT identification number; • month and year of manufacture (including the words *Date of Manufacture, Month, Year*) in 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; • month and year of expiry (including the words *Expiry Date, Month, Year*) 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; • manufacturer's name and registered address; • nominal width of the condom, expressed in millimeters; • number of condoms in box; • instructions for storage. **Note: All markings must be legible.** Inner box markings can be specified in accordance with program requirements.
information	If, in accordance with local regulations or program requirements, informationis to be provided with the condom, then the following instructions should be considered for inclusion: • to handle the condom carefully, including removal from the package so as to avoid damage to the condom by fingernails, jewellery, etc.; • 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; • to stop and check if the user feels the condom slipping, as it may fall off the penis; • to stop and check if the user feels the condom tightening excessively on the penis, as this may lead to breakage; • to withdraw the penis soon after ejaculation, while holding the condom firmly in place at the base of the penis; • 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; • to consult a doctor or pharmacist about the compatibility of topical medicines that might come in contact with the condom; • to seek medical assistance at soon as possible within five days, should a condom leak or burst during use; • if the individual container is obviously damaged, to discard that condom and use a new one from an undamaged package; • instructions on how to dispose of the used condom; • a statement that the condom is for single use; • the number of the International Standard, i.e. *ISO 4074*. ***It is recommended*** **that the following statement relating to the safety and effectiveness of the condom be included:** **"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."**
exterior shipping cartons	The inner boxes shall be packed into plastic or other waterproof lining bags, which will be placed in three-wall cartons made from weather-resistant corrugated fiberboard with a bursting test strength of not less than 1900 kPa. The carton flaps shall be secured with water-resistant adhesive applied to not less than 75% of the area of contact between the flaps, or with 75 mm wide water-resistant tape

	applied to the full length of the centre seams and extending over the ends by not less than 75 mm. The cartons may be secured by plastic strapping at not less than two positions. Alternatively, wire-bound, cleated plywood or nailed wood boxes are acceptable when lined with a waterproof barrier material. The barrier material must be sealed at the edges with waterproof tape or adhesive, and there must be no sharp protrusions inside the boxes. In some countries the three-wall corrugated fiberboard 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 fiberboard shall be inserted into the shipping carton before packing the condoms. 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: • LOT identification number; • month and year of manufacture (including the words *Date of Manufacture, Month, Year*) 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; • month and year of expiry (including the words *Expiry Date, Month, Year*) 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; • name and address of supplier; • nominal width; • number contained in the carton; • instructions for storage and handling. To facilitate monitoring of LOT quality during shipping and storage, all exterior shipping cartons for each discrete LOT shall be assembled and shipped together.
lot traceability	Best efforts shall be made to ensure that shipments remain as discrete LOTS and that these LOTS remain intact as far down the distribution system as possible. These efforts may include the use of very large lettering for LOT codes on the exterior shipping cartons; colour coding; using one pallet per LOT; physically linking all exterior shipping cartons from discrete LOTS; and issuing instructions to this effect to shippers and warehouse personnel.

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**
contents	Number of condoms not as specified; packages or strips not as specified.
marking	Omitted; incorrect; illegible; of an improper size (exterior, interior), incorrect location, sequences, or method of application.
materials	Packaging/packing materials not as specified, missing, damaged or non-serviceable.
workmanship	Shipping cartons inadequately closed and secured; poor application of internal packaging and packing material; distorted intermediate packages.

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

table 2. summary of prequalification tests and requirements		
sample according to Annex B of *ISO 4074* for "isolated Lots" and *ISO 2859–1*		
test	**sampling**	**requirements**
Verification of constituent	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. **16.0** dm^3 for condoms with widths less than 50 mm 2. **18.0** dm^3 for condoms with widths from 50 mm to 55.5 mm 3. **22** dm^3 for condoms with widths greater than 56 mm AQL 1.5
Bursting pressure (before and after oven conditioning)	Level G-I Minimum Code Letter M	Minimum pressure: 1.0 kPa AQL 1.5
Freedom from holes (before and after oven conditioning for (168 ± 5) h at (70 ± 2) °C)	Level G-I Minimum Code Letter N	AQL 0.25
Visible defects (before and after oven conditioning for (168 ± 5) h at (70 ± 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 ± 5) h at (70 ± 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	± 2 mm of claimed width AQL 1.0
Length	Level S-2	1. **165** mm for widths less than 50 mm 2. **180** mm for widths between 50 mm and 55.5 mm 3. **190** 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. **16.0** dm^3 for condoms with widths less than 50 mm 2. **18.0** dm^3 for condoms with widths from 50 mm to 55.5 mm 3. **22** dm^3 for condoms with widths greater than 56 mm AQL 1.5
Bursting pressure (before and after oven conditioning)	Level G-I	Minimum pressure: 1.0 kPa AQL 1.5
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. **165** mm for widths less than 50 mm 2. **180** mm for widths between 50 mm and 55.5 mm 3. **190** 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
Individual package materials and markings	Level S-3	Compliant with procurement specifications AQL 2.5

Technical Specification: TCu380A Intrauterine Device (IUD)

(From WHO draft TCU380A IUD Specification Document May 2010)

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 mm2 and copper wire of 310 mm2 surface area wound tightly around the vertical stem, giving a total surface area of 380 mm2, 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.

It is recommended that all biological safety in accordance with ISO 10993 parts 1, 3, 5, 10 and 11 is conducted by accredited laboratories.

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. The compounded polymer (LDPE plus barium sulphate) shall be evaluated for biological safety in accordance with ISO 10993-1 requirements for mucosal membrane contact devices intended for permanent contact. Specifically the following testing is required:

- Testing for geno-toxicity according to ISO 10993-3
- Testing for cyto-toxicity testing according to ISO 10993-5
- Testing for irritation and delayed-type hypersensitivity according to ISO 10993-10
- Testing for sub-acute and sub chronic toxicity according to ISO 10993-11

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 ± 0.005) mm (30 AWG[29], 33 ISWG[30]).

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[3]. The collars shall be manufactured from copper tube half hard temper with internal diameter (1.68 ± 0.025) mm and external diameter: (2.2 ± 0.025) mm. The collars shall be (5 ± 0.15) mm in length.

The collars shall be de-burred, 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.

The compounded polymer (HDPE plus titanium dioxide) shall be evaluated for biological safety in accordance with ISO 10993-1 requirements for mucosal membrane contact devices intended for permanent contact. Specifically the following testing is required:

- Testing for geno-toxicity according to ISO 10993-3
- Testing for cyto-toxicity testing according to ISO 10993-5
- Testing for irritation and delayed-type hypersensitivity according to ISO 10993-10
- Testing for sub-acute and sub chronic toxicity according to ISO 10993-11

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 ± 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 ± 0.1) mm and outside diameter of (4.4 ± 0.1) mm.

2.6 Insertion rod

Food contact grade radiation stable ABS (Acrylonitrile-Butadiene-Styrene polymer) or food

[29] American Wire Gauge

[30] Imperial Standard Wire Gauge

contact grade radiation stabilized polypropylene (PP) with a tip diameter of (2.6 ± 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) shall be subjected to *in vitro* cyto-toxicity testing in accordance with ISO 10993 - 5 (Biological evaluation of medical devices — Part 5: Tests for in vitro cyto-toxicity).

The cytotoxic response shall not be worse than that recorded for the compounded material when originally evaluated for biological safety according to the requirements of ISO 10993-1.

The barium sulphate content of the frame material shall 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 moulded 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 ± 0.5) mm
- Length of vertical stem: (36 ± 0.5) mm
- Diameter of horizontal arm: (1.6 ± 0.1) mm
- Diameter of vertical stem: (1.5 ± 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 ± 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 mm ± 0.7 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 radiussed 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 ± 0.15) mm
- Collar weight: (68.7 ± 3.0) mg
- Collar Position: 5.4 ± 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 ± 2) mm

Internal Diameter: (3.7 ± 0.1) mm Outside Diameter: (4.4 ± 0.1) mm

6.7 Insertion rod

Length: (190 ± 5) mm from handle brace to tip. Diameter at tip: (2.6 ± 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 ± 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 mm2 ± 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 ± 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± 2C°.

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 ± 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 ± 2) °C. Before testing the T frames shall be stored for at last 6 hours at the test temperature.

A suitable test rig may be used to clamp the T frame and measure the amplitude of the defection. 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. 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^{0} 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^{0}).

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 purchaser. 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 offer or(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 purchaser for each lot intended for shipment.

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

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

17.3 Inspection by the Purchaser

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

17.4 Sampling Procedures

The purchaser or the purchaser'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

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 c**onsists 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-butadienestyrene 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

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 90⁰ 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 180⁰).

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 purchaser.

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 10-6.

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 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 any time 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 offer or(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 GMPs. 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 purchaser for each lot intended for shipment.

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

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

Inspection by the Purchaser

The purchaser 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 purchaser 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 purchaser 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 purchaser may have some or all of the tests specified in the contract performed by a laboratory suitably equipped and qualified to conduct QA tests on implants.

Sampling Procedures

The purchaser or the purchaser'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: Emergency contraceptive Pills

General Description

There are three types of ECPs: combined ECPs containing both, estrogen and progestin, progestin-only ECPs, and ECPs containing an anti-progestin. Progestin-only ECPs have now largely replaced the older combined ECPs because they are more effective and cause fewer side effects. Although this therapy is commonly known as the morning-after pill, the term is misleading; ECPs may be initiated sooner than the morning after—immediately after unprotected intercourse—or later—for at least 120 hours after unprotected intercourse.

Progestin-only ECPs contain no estrogen. Only the progestin levonorgestrel has been studied for freestanding use as an emergency contraceptive. The original treatment schedule was one 0.75 mg dose within 72 hours after unprotected intercourse, and a second 0.75 mg dose 12 hours after the first dose. However, recent studies have shown that a single dose of 1.5 mg is as effective as two 0.75 mg doses 12 hours apart.[31]

The antiprogestin mifepristone has also been extensively studied for use as an emergency contraceptive pill. Mifepristone is a first generation progesterone receptor modulator. A second generation antiprogestin, ulipristal acetate (30 mg in a single dose), has been studied for use as emergency contraception and has been found to be highly effective and well tolerated.[32] However both these products are not registered in Pakistan

1. Requirements

Emergency contraceptive tablets in accordance with the following specifications:

- *Each tablet shall contain 0.753 mg of Levonorgestrel*

1.1 Product and Brand Names

- Product name: ……
- Brand names: ……..
- Registration Number: ……..

1.2 Raw Materials

Emergency contraceptive tablets offered under this purchase description shall be produced from validated raw materials obtained from a licensed manufacturer or its authorized

[31] Von Hertzen H, Piaggio G, Ding J, Chen J, Song S, Bártfai G, Ng E, Gemzell-Danielsson K, Oyunbileg A, Wu S, Cheng W, Lüdicke F, Pretnar-Darovec A, Kirkman R, Mittal S, Khomassuridze A, Apter D, Peregoudov A. Low dose mifepristone and two regimens of levonorgestrel for emergency contraception: a WHO multicentre randomised trial. Lancet. 2002;360:1803-10.

Arowojolu AO, Okewole IA, Adekunle AO. Comparative evaluation of the effectiveness and safety of two regimens of levonorgestrel for emergency contraception in Nigerians. Contraception. 2002;66:269-73.

[32] Creinin MD, Schlaff W, Archer DF, Wan L, Frezieres R, Thomas M, Rosenberg M, Higgins J. Progesterone receptor modulator for emergency contraception: a randomized controlled trial. Obstet Gynecol. 2006;108:1089-97.

Fine P, Mathé H, Ginde S, Cullins V, Morfesis J, Gainer E. Ulipristal acetate taken 48-120 hours after intercourse for emergency contraception. Obstet Gynecol. 2010;115:257-63.

Glasier AF, Cameron ST, Fine PM, Logan SJ, Casale W, Van Horn J, Sogor L, Blithe DL, Scherrer B, Mathe H, Jaspart A, Ulmann A, Gainer E. Ulipristal acetate versus levonorgestrel for emergency contraception: a randomised non-inferiority trial and meta-analysis. Lancet. 2010;375:555-62.

distributor.[33]

1.3 Registration Requirements

Emergency contraceptives offered under this purchase description shall be currently registered in Pakistan and approved by the Ministry of Health under the Drugs Act, 1976.

1.4 Certificate of Registration Status in Country of Origin (in case of imported drugs)

Emergency contraceptives 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 offer or(s) may be required to submit a "statement of licensing status of pharmaceutical product(s)" as provided under the World Health Organization (WHO) Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce.[34]

1.5 Compliance with Current Good Manufacturing Practices

The Supplier must be able to provide certification that the oral contraceptives are manufactured according to WHO current cGMPs. Such certification can be found in the WHO Certification Scheme "Certificate of Pharmaceutical Product." Supplier also must be able to provide copies of its annual cGMP audit reports conducted by the local Drug Regulatory Authority.

1.6 WHO Certification—Movement in International Commerce

The Supplier must be able to provide documentation indicating that the manufacturer of the product has received confirmation from the Ministry of Health of the country of manufacture that the pharmaceutical meets the requirements in the WHO Certification Scheme.

1.7 Shape and Dimensions

Tablets shall be of the shape and dimensions of the bidder's normal, standard commercial tablets which are available in the local market.

1.8 Colors

Emergency contraceptives tablets shall be similar to bidder's normal, standard commercial tablets.

1.9 Tablet Markings

Each tablet shall bear the identifying imprint of its manufacturer.

1.10 Packaging

Each individual tablet shall be enclosed in a transparent blister pack of thermoformed polymer, with a minimum thickness of 0.1905 mm (.0075 inch) backed with aluminum foil, minimum

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[33] Because the raw materials that make up both active and inactive ingredients are of great importance for final product bioavailability and stability, current good manufacturing practices require that manufacturers validate vendors for all raw materials. A typical validation includes, but is not limited to, these areas:

- Manufacturing records and procedures for raw materials synthesis, processing, packing and storage.
- Quality control records and procedures for the raw materials, in-process and final product.
- Plant certification by local regulatory authorities (such as commerce, industry, health, labour, environment) as required.
- Certification of workers' training in current good manufacturing practices and safety protection.
- Records demonstrating raw materials with the required physical and chemical characteristics.

[34] Available at: http://www.who.int/medicines/areas/quality_safety/regulation_legislation/certification/en/index.html.

thickness 0.0178 mm (0.0007 inch). Variations must be proven scientifically comparable by means of stability data.

The size of the package shall not be less than 57.15 mm (2.25 inches) x 82.55 mm (3.25 inches). Thicker polymer or foil or the addition of a card to either the front or the back of the package (in addition to the minimum polymer or foil) is acceptable.

1.11 Identification Markings on Individual Blister Packs

Each individual blister pack shall have the following information:

- Product/brand name
- Lot/batch number
- Expiration date (day, month and year)
- Date of manufacture
- Manufacturer's name and address
- Contents and quantity, including tablet formulation (amounts of active ingredients per tablet)
- Drug registration number (if applicable)
- Family planning logo (if applicable)
- Drug Manufacturing License Number
- Product use and storage instructions (accompanying the blister pack).

1.12 Workmanship

Products and packaging shall be free of defects that impair their serviceability, affect their durability, or detract from their appearance.

1.13 Lots per Order

The Supplier shall fill the order using the fewest number of manufacturing lots possible.

1.14 Shelf Life

The shelf life of the product provided under this solicitation shall *be five (5)* years from the date of manufacture when stored under tropical conditions such as those prevailing in the local environment. The Supplier shall be able to provide to the satisfaction of the registration/national QC authorities the manufacturers' stability test data substantiating this *five (5)* year shelf life at ambient temperatures at or greater than 32 degrees Celsius and at a relative humidity of 85% in the proposed blister package.

At the time of inspection or acceptance for delivery to the country of destination, no more than *nine (9) months* shall have expired since the date of manufacture shown on the batch release or Certificate of Analysis.

1.15 Test Data

Chemical and physical test data for raw materials, components in-process and finished product testing must be on record for each lot manufactured and must be available to purchaser's representatives when requested.

2. Quality Assurance Provisions

Same as Oral Contraceptive Pills

3. Packing

Same as Oral Contraceptive Pills

Inspection Sampling and Testing

Same as Oral Contraceptive Pills

Sample Forms

The following sample forms should be included in the bidding documents package as required by the specific procurement activity being conducted:

- Bid Submission Form
- Price Schedule for Contraceptives Manufactured outside of Pakistan
- Price Schedule for Domestic Contraceptives Manufactured within Pakistan
- Manufacturer's Authorization
- Bid Security Form (Bank Guarantee)
- Bid Security (Bid Bond)
- Form of Contract Agreement
- Performance Security Bank Guarantee
- Bank Guarantee Form for Advance Payment
- Certificate of a Pharmaceutical Product

BID COVER SHEET

Bid Ref. No._____ Date_____

Name of the Supplier/Firm Contractor: _____

Address:_____

_____

E-mail:_____

Phone: _____

Facsimile: _____

Bid Security attached with Financial Bid YES NO

Bid for:

†: All Items mentioned in the Schedule of Requirements.

†: Selected Items from the Schedule of Requirements[35].

List of Selected Items: *(In case the Bidder has opted to bid for Selected Items, please type the Serial No[36]. and the name of the Items selected for Bidding. Use additional Sheets if Required)*

S. No.	*Name of the Item*	*Batch Capacity of the Drug/Medicine/Product*	*Trade Price*	*MRP*

Signed:

Dated:

Official Stamp:

Attachment[37]: †*Original receipt for the purchase of the bidding documents*.

[35] *In case a bidder is bidding for only some of the items mentioned in the list Technical Specifications , he is advised to take note of ITB Clauses 7 & 17.10*

[36] *The Serial No. of the item as mentioned in the Technical Specifications.*

[37] The Attachment must be made with the Bid Cover Sheet.

BID FORM 1 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 price schedule or such other sums as may be determined in accordance with the terms and conditions of the Contract. The above amounts are in accordance with the Price Schedules attached herewith and are made part of this bid.

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

If our bid is accepted, we undertake to provide a performance security/guaranty in the form, in the amounts, and within the times specified in the bidding documents.

We agree to abide by this bid, for the Bid Validity Period specified in 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 confirm that we comply with the eligibility requirements as per ITB clauses 2,3 & 4 of the bidding documents.

We, have nationalities from eligible countries, in accordance with ITB Sub-Clause 2.2: *[insert the nationality of the Bidder, including that of all partners in case of a Joint Venture /Consortium if applicable];*

We, for any part of the contract resulting from this IFB, do not have any conflict of interest;

Dated thi*s [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]*

AFFIDAVIT FORM

On Judicial Paper

I/We, the undersigned solemnly state that:

1) We 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 we propose to supply under this contract are eligible goods within the meaning of Clause 2 of the ITB.
4) The undersigned are also eligible Bidders within the meaning of Clause 2of the ITB.
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 the prices offered are not more than trade price.
9) I / We, further undertake that the prices given are reasonable and not given more than in any Government/Autonomous/District Government institutions in Pakistan during the current financial year. If any difference detected, the firm is bound to refund the difference in price.
10) We further undertake that we have not been involved in any litigation during last three years.

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

Signed

BID FORM 3(A)

Name of the Firm

Bid Reference No:

Date of opening of Bid.

Documentary Evidence: Eligibility of the Bidders and Goods

Required Documentation in accordance with Bid Evaluation Criteria of the Bidding Documents *(To Be Filled by the Procuring Agency)*	Checklist[38] *(To be initialed by the Bidder against each document)*	Relevant Page Number[39] in the Bid *(To be filled by the Bidder)*	Supporting Documents[40] *(To be filled by the Bidder with name of the documents that are submitted to meet the requirement)*
Column:1	**Column:2**	**Column:3**	**Column:4**
"Nationality" as required under 1.1 of Technical Evaluation Criteria – Required Documents are Bid Form 1 & Form ELI-1.1			
"Conflict of Interest" as required under 1.2 of Technical Evaluation Criteria –Required Documents are Bid Form 1& Form ELI-1.1			
"Not Declared Ineligible" as required under 1.3 Technical Evaluation Criteria –Required Document is an Affidavit (Form ELI-1.2)			
"WHO Prequalification" as required under 1.4 of Technical Evaluation Criteria –Required Document is Form ELI-1.3			
"**Undertaking** regarding "Lab Testing of Locally Manufactured Contraceptives" as required under			

[38] Bidders should only initial against those requirements that they are attaching with the form 3(a). In case they do not have any document to attach the corresponding cell in column 2 should be left blank.
[39] Bidders are required to mention the exact page number of relevant document placed in the Bid.
[40]Bidders are advised to attach all Supporting documents with this form in the order of the requirement as mentioned in column 1.

1.5 of Technical Evaluation Criteria –Required Document is an Affidavit.			
"Valid cGMP/CE/FDA/Equal Manufacturer's Country Quality Assurance Certificate" as required under 1.6 of Technical Evaluation Criteria –Required Document is a			
DRAP registration application (for Foreign Bidders, if applicable) as required under 1.7 of Technical Evaluation Criteria – Required Document is a copy of application/certificate.			
Valid Manufacturing License as required under 1.8 of Technical Evaluation Criteria –Required Document is a copy of valid certificate.			
"Audited Balance Sheet along with Income Tax Return" for up to last three years" as required under 2.1 of Technical Evaluation Criteria –Required Document is Form FIN-2.1 (a) with attachments.			
"Annual turnover/Sales Value" as required under 2.2 of Technical Evaluation Criteria –Required Document is Form FIN-2.1 (b) with attachments.			
"Specific Supplies Experience" as required under 2.3 of Technical Evaluation Criteria –Required Document is Form EXP 3.2 with attachments.			
"Production Capacity" as required under 2.4 of Technical Evaluation Criteria –Required Document is Form EXP 3.3 with attachments.			
"Valid ISO Certificate" as required under 2.5 of Technical Evaluation Criteria –Required Document is a copy of valid certificate.			
Valid Registration(s) of quoted items			

Valid Drugs Sale License[41]			
WHO prequalification certification[42]			
Valid Import License (where applicable)			
Letter of Manufacturer's authorization (Where Applicable)			
Partnership Deed (where applicable)			
NTN Certificate			
GST Certificate			
Letter of Intention			
Affidavit			
Child Labor Free Certificate[43]			
Original Receipt of purchase of Bidding Documents			

[41] In case of Sole Importer/Representative

[42] WHO prequalification certification required for imported products.

[43] Bidders are required to furnish a certificate to the effect that their firm is free from child labor and having standard child labor free policy

Bid Form ELI -1.1
Bidder Information Form

Date: _ _/_ _/*2015*
IFB No. and title: (*insert IFB number*), Procurement of Contraceptives
Page *[insert page number]* of *[insert total number]* pages

Applicant's legal name *[insert full legal name]*
In case of Joint Venture (JV), and consortium legal name of each partner: *[insert full legal name of each partner in JV]*
Applicant's Actual or Intended country of constitution: *[indicate country of Constitution]*
Applicant's actual or Intended year of constitution: *[indicate year of Constitution]*
Applicant's legal address in country of constitution: *[insert street/ number/ town or city/ country]*
Applicant's authorized representative information Name: *[insert full legal name]* Address: *[insert street/ number/ town or city/ country]* Telephone/Fax numbers: *[insert telephone/fax numbers, including country and city codes]* E-mail address: *[indicate e-mail address]*
Attached are copies of original documents of ☐ Articles of Incorporation or Documents of Constitution, and documents of registration of the legal entity named above. ☐ In case of JV, letter of intent to form JV or JV agreement.

Form ELI -1.2
Affidavit

(Not Declared Ineligible)

a) Applicants signed affidavit on judicial paper confirming not having been declared ineligible by any of the public sector organization in Pakistan, as described in ITB Sub-Clause 2.3

b) Applicants signed affidavit on judicial paper confirming not having been involved in any litigation during last three years.

Form ELI -1.3

Bidder's Information Form

Date: *[insert day, month, year]*
IFQ No. and title: (*insert IFQ number*)„ Procurement of Contraceptives
Page *[insert page number]* of *[insert total number]* pages

1	Applicant's Primary Business Details	1	
		2	
		3	
		4	
2	List of Products / Services	1	
		2	
		3	
		4	
3	List of Authorization from the principals	1	
		2	
		3	
		4	
5	Warranty Details		
6	Return/Replacement Policy		
7	cGMP certification		
8	Installed annual production capacity		
9	Certification of WHO prequalification[44]		
10	Any Other Information that supplier may like to provide		

[44] *For international manufacturers only*

Form FIN – 2.1 (a)

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: (*insert IFB number*)„ Procurement of Contraceptives
Page *[insert page number]* of *[insert total number]* pages_____

1. Financial data

Financial information in (PKR/US$ equivalent in 000s)	**previous** *_[insert number] years, years information [insert in words]* **(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)[45] (TA – TL)					
Current Assets (CA)					
Current Liabilities (CL)					
Working Capital[46] (CA – CL)					
Information from Income Statement					
Total Revenue (TR)					
Profits Before Taxes (PBT)					

[45] **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.
[46] **Working capital** is the difference between current assets and current liabilities, and measures the firm's ability to generate cash in the short term.

2. Financial documents

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 FIN - 2.1 (b)

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**
[indicate year]	*[insert amount and indicate currency]*	*[insert amount in PKR/US$ equiv.]*
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 EXP - 3.2

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

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

Form EXP - 3.2 (cont.)

Specific Experience (cont.)

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

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

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

Form EXP - 3.3

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: *[insert peak and average production capacity over the last three years in units/day or units/month, etc.]*
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 3(B) MANUFACTURER'S AUTHORIZATION[47]

(For Foreign Bidders)

To: [Name & Address of the Procuring Agency]

WHEREAS *[name of the Manufacturer]* who are established and reputable Manufacturers of *[name and/or description of the goods]* having factories at *[address of factory]* do hereby authorize *[name and address of Supplier/ Representative]* to submit a bid, and subsequently negotiate and sign the Contract with you against the Invitation for Bids (IFB) No. *[Reference of the Invitation to Bid] for* the goods manufactured by us.

We hereby extend our full guarantee and warranty as per Clause 15 of the General Conditions of Contract for the goods offered for supply by the above firm against this Invitation for Bids.

Signature:_____

Designation:_____

Official Stamp:_____

Notes on Manufacturer's Authorization Form

The bidder shall require the Manufacturer to fill in this Form in accordance with the instructions indicated. This letter of authorization should be on the letterhead of the Manufacturer and should be signed by a person with the proper authority to sign documents that are binding on the Manufacturer. The bidder shall include it in its bid, if so indicated in the BDS.

[47] *This letter of authority should be on the letterhead of the Manufacturer and should be signed by a person competent and having the power of attorney to bind the Manufacturer. It should be included by the Bidder in its bid.*

BID FORM 4 Firm's Past Performance[48].

Name of the Firm:

Bid Reference No:

Date of opening of Bid: _____**2015**

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[49] Certificate

[48] *Bidders may use additional Sheets if required.*
[49] *All certificates are to be attached with this form.*

BID FORM 5(A) Price Schedule

User Note: *This form is to be filled by the Bidder for each individual item and shall submit with Financial Proposal.*

Name of the Firm:_____

Bid Ref No:_____

Date of opening of Bid._____

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					

A) FINAL TOTAL PRICE: _____

B) DISCOUNT[50]:_____

C) FINAL QOUTED PRICE: _____

(C=A-B)

Signature: _____

Designation: _____

Date: _____

Official Stamp

[50] *If a Bidder does not wish to offer an item wise discount but intends to offer an overall discount to its quoted price that should be mentioned here.*

BID FORM 5(B) (Price Analysis)

(*User Notes):*

1. This form is to be filled by the Bidder <u>for each individual item</u> and shall submit with Financial Proposal.

Name of the Firm:_____

Bid Reference No:_____

Date of opening of Bid._____

Sl. No.	Name of the Item	Unit Price						Total Price /Unit	No. of Units	Total Price
		Ex-factory, Ex Ware house, (Domestic) or CPT/CFR (international)	Sales and Income Tax	Other Levies and Duties *(if any)*	Packaging	Transportation Costs incidental to delivery	Other Incidental Costs as defined in the Schedule of Requirement			
		a	b	c	d	e	f	g g=a+b+c+d+e+f	h	i i = g*h

Signature:_____

Designation:_____

Date:_____

Official Stamp

Bid Security Form (Bank Guarantee)

(The Bank shall fill in this Bank Guarantee Form in accordance with the instructions indicated.)

_____

(insert Bank's Name, and Address of Issuing Branch or Office)

Beneficiary: (*insert name of Respective Procuring Agency*) Peshawar, Pakistan _____

Date: _____

BID GUARANTEE No.: _____

We have been informed that (*insert name of the bidder*) (hereinafter called "the bidder") has submitted to you its bid dated (hereinafter called "the Bid") for the execution of (*insert name of contract*) under Invitation for Bids No. (*insert IFB number*) ("the IFB").

Furthermore, we understand that, according to your conditions, bids must be supported by a bid guarantee.

At the request of the bidder, we (*insert name of Bank*) hereby irrevocably undertake to pay you any sum or sums not exceeding in total an amount of (*insert amount in figures*) (*insert amount in words*) upon receipt by us of your first demand in writing accompanied by a written statement stating that the bidder is in breach of its obligation(s) under the bid conditions, because the bidder:

(a) has withdrawn its Bid during the period of bid validity specified by the bidder in the Form of Bid; or

(b) having been notified of the acceptance of its Bid by the purchaser during the period of bid validity, (i) fails or refuses to execute the Contract Form, if required, or (ii) fails or refuses to furnish the performance security, in accordance with the Instructions to bidders.

This guarantee will expire: (a) if the bidder is the successful bidder, upon our receipt of copies of the contract signed by the bidder and the performance security issued to you upon the instruction of the bidder; or (b) if the bidder is not the successful bidder, upon the earlier of (i) our receipt of a copy of your notification to the bidder of the name of the successful bidder; or (ii) twenty-eight days after the expiration of the bidder's Bid.

Consequently, any demand for payment under this guarantee must be received by us at the office on or before that date.

This guarantee is subject to the Uniform Rules for Demand Guarantees, ICC Publication No. 458.

_____

(signature(s)

Form of Contract Agreement

THIS CONTRACT AGREEMENT is made

on the (insert: number) day of *(insert: month)*, (*insert: year*).

BETWEEN

(1) *(insert: Name of purchaser)*, a *(insert: description of type of legal entity, for example, an agency of the Ministry of .... of the Government of (insert: country of purchaser)*, and having its principal place of business at *(insert: address of Procuring Agency)* (hereinafter called "the *Procuring Agency*)"), and

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

WHEREAS the purchaser invited bids for certain contraceptives and ancillary services, viz., (*insert: brief description of contraceptives and services*) and has accepted a bid by the Supplier for the supply of those contraceptives and services in the sum of *(insert: contract price in words and figures*) (hereinafter called "the Contract Price").

NOW THIS AGREEMENT WITNESSETH AS FOLLOWS:

1. In this Agreement words and expressions shall have the same meanings as are respectively assigned to them in the Conditions of Contract referred to.

2. The following documents shall constitute the Contract between the purchaser and the Supplier, and each shall be read and construed as an integral part of the Contract:

This Contract Agreement

Special Conditions of Contract

General Conditions of Contract

Technical Requirements (including Technical Specifications) The Supplier's bid and original Price Schedules

The purchaser's Notification of Award

(*Add here: any other documents*)

3. In consideration of the payments to be made by the purchaser to the Supplier as hereinafter mentioned, the Supplier hereby covenants with the purchaser to provide the contraceptives and Services and to remedy defects therein in conformity in all respects with the provisions of the Contract.

4. The purchaser hereby covenants to pay the Supplier in consideration of the provision of the contraceptives and the remedying of defects therein, the Contract Price or such other sum as may become payable under the provisions of the Contract at the times and in the manner prescribed by the Contract.

For and on behalf of the purchaser

Signed: _____

in the capacity of (*insert: title or other appropriate designation*)

in the presence of _____

For and on behalf of the Supplier

Signed: _____

in the capacity of *(insert: title or other appropriate designation*)

in the presence of _____

CONTRACT AGREEMENT

Performance Guarantee

To: *[Name & Address of the Respective Procuring Agency]*

Whereas *[Name of Supplier]* (hereinafter called "the Supplier") has undertaken, in pursuance of Contract No. *[Number]* dated *[date]* to supply *[description of goods]* (hereinafter called "the Contract").

And whereas it has been stipulated by you in the said Contract that the Supplier shall furnish you with a Bank Guarantee by a scheduled bank for the sum of **10%** of the total Contract amount as a Security for compliance with the Supplier's performance obligations in accordance with the Contract.

And whereas we have agreed to give the Supplier a Guarantee:

Therefore we hereby affirm that we are Guarantors and responsible to you, on behalf of the Supplier, up to a total of *[Amount of the Guarantee in Words and Figures]* and we undertake to pay you, upon your first written demand declaring the Supplier to be in default under the Contract and without cavil or argument, any sum or sums within the limits of *[Amount of Guarantee]* as aforesaid, without your needing to prove or to show grounds or reasons for your demand or the sum specified therein.

This guarantee is valid until the_____ day of_____, 201_

Signature and Seal of the Guarantors/ Bank

Address_____

Date _____

Integrity Pact

DECLARATION OF FEES, COMMISSION AND BROKERAGE ETC

PAYABLE BY THE SUPPLIERS/CONTRACTORS/CONSULTANTS

Contract Number: _____ Dated: _____

Contract Value: _____

Contract Title: _____

[*Name of Supplier/Contractor*] hereby declares that it has not obtained or induced the procurement of any contract, right, interest, privilege or other obligation or benefit from Government of Khyber Pakhtunkhwa or any administrative subdivision or agency thereof or any other entity owned or controlled by it through any corrupt business practice.

Without limiting the generality of the foregoing, [*Name of Supplier/Contractor*] 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, representative, 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 Procuring Agency, except that which has been expressly declared pursuant hereto.

[Name of Supplier/Contractor] certifies that it has made and will make full disclosure of all agreements and arrangements with all persons in respect of or related to the transaction with Procuring Agency and has not taken any action or will not take any action to circumvent the above declaration, representation or warranty.

[*Name of Supplier/Contractor*] 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.

Notwithstanding any rights and remedies exercised by Procuring Agency in this regard, [*Name of Supplier/Contractor*] 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 time the sum of any commission, gratification, bribe, finder's fee or kickback given by [*Name of Supplier/Contractor*] 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.

_____ _____

[*Procuring Agency*] [*Supplier /Contractor*]

CHECK LIST OF DOCUMENTS PROVIDED WITH PAGE MARKING

No	Description	Documents Attached		
		Yes	No	Page No.
1)	Receipt of the bidding document Purchase			
2)	Name of the signatory of the firm with CNIC copy			
3)	2 -% bid security attached with the Financial bid (in original)			
4)	Name & pack size of the Product offered are clearly mentioned in the technical bid			
5)	Drug Registration bearing latest price of the contraceptive enclosed (specific items)			
6)	Undertaking on judicial stamp paper regarding potency of the drug and fit for human use/consumption.			
7)	Undertaking on judicial stamp paper that the firm participating in the tender has not been black listed/suspended the license by any Government/Institution/organization etc..			
8)	Undertaking on judicial stamp paper that no violation of child labor in the firm			
9)	For repacking item the bidder has enclosed the valid License/Excise license & relevant documents etc.			
10)	For imported drugs / Products Certificate of analysis from country of origin.			
11)	For imported drugs/products Free Sale Certificate from country of origin			
12)	For imported drugs/products valid Authority letter duly authenticated by Pakistan Embassy at the Country of Origin.			
13)	All Bid Forms as mentioned in Section VII of the Bidding Documents.			
14) 15)				

List of WHO Pre-qualified Labs for contraceptive quality control

No	Quality Control Test Facility	Product
1	FHI 360 Product Quality and Compliance 2810 Meridian Parkway, Suite 160 Durham, NC 27713 USA Emails: shamel@fhi360.org, jtremelling@fhi360.org Bangkok Laboratory: FHI 360 Product Quality and Compliance Bangkok, Thailand Emails: shamel@fhi360.org, jtremelling@fhi360.org	Male and female condoms Oral and injectable contraceptives IUDs
2	Enersol 235 Nelson Street, Annandale, NSW 2038 AUSTRALIA Phone: (+61) 2 9552 1707 Fax: (+61) 2 9552 1709 E-mail: enquiries@enersol.com.au Malaysian Laboratory: Enersol No. 2-2, Lebuh 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	Male and female condoms IUDs, Syringes, Infusion sets, needles, blood bags, catheters and gloves
3	Valendor AB Vargmötesvägen 4 186 30 Vallentuna Sweden Phone: +46(0)8 514 302 44 www.valendor.se	Male and female condoms Gloves
4	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	Male and female condoms
5	TÜV SÜD PSB Pte Ltd Chemical & Materials (Food & Pharmaceutical Testing) 1 Science Park Drive Singapore 118221 Tel: +65 68851313 Fax: +65 67784301 e-mail: enquiries@tuv-sud-psb.sg , http://www.tuv-sud-psb.sg	Male and female condoms, IUDs, Pharmaceutical Hormonal Contraceptives

Certificate of a Pharmaceutical Product[1]

This certificate conforms to the format recommended by the World Health Organization

(general instructions and explanatory notes attached).

No. of certificate: _____

Exporting (certifying) country: _____

Importing (requesting) country: _____

1. Name and dosage form of product:

_____

1.1 Active ingredients[2] and amount(s) per unit dose.[3]

_____

_____

_____

For complete qualitative composition including excipients, see attached.[4]

1.2 Is this product licensed to be placed on the market for use in the exporting country?[5] yes/no (*key in as appropriate*)

1.3 Is this product actually on the market in the exporting country? yes/no/unknown

(key in as appropriate)

2. If the answer to 1.2 is yes, continue with section 2A and omit section 2B. If the answer to 1.2 is no, omit section 2A and continue with section 2B.[6]

2A.1 Number of product license7 and date of issue:

_____

2A.2 Product-license holder (name and address):

_____

_____

_____

2A.3 Status of product-license holder:8 a/b/c (*key in appropriate category as defined in note 8*)

2A.3.1 For categories b and c the name and address of the manufacturer producing the dosage form are:[9]

2A.4 Is Summary Basis of Approval appended?10 yes/no (*key in as appropriate*)

2A.5 Is the attached, officially approved product information complete and consonant with the license?11 yes/no/not provided (*key in as appropriate*)

2A.6 Applicant for certificate, if different from license holder (*name and address*):12

2B.1 Applicant for certificate (*name and address*):

2B.2 Status of applicant: a/b/c (key in appropriate category as defined in note 8)

2B.2.1 For categories b and c the name and address of the manufacturer producing the dosage form are:9

2B.3 Why is marketing authorization lacking?

not required/not requested/under consideration/refused (*key in as appropriate*)

2B.4 Remarks:13

3. Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced? yes/no/not applicable14 (*key in as appropriate*)

If no or not applicable, proceed to question 4.

3.1 Periodicity of routine inspections (years):

3.2 Has the manufacture of this type of dosage form been inspected?

yes/no (*key in as appropriate*)

3.3 Do the facilities and operations conform to GMP as recommended by the World Health Organization?15

yes/no/not applicable16 (*key in as appropriate*)

4. Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product? 11

yes/no (key in as appropriate)

If no, explain: _____

_____

Address of certifying authority: _____

Telephone number: _____ Fax number: _____

Name of authorized person: _____

Signature:

_____

Stamp and date:

_____

General instructions

Please refer to the guidelines for full instructions on how to complete this form and information on the implementation of the Scheme.

The forms are suitable for generation by computer. They should always be submitted as hard copy, with responses printed in type rather than handwritten.

Additional sheets should be appended, as necessary, to accommodate remarks and explanations.

Explanatory notes

[1] *This certificate, which is in the format recommended by WHO, establishes the status of the pharmaceutical product and of the applicant for the certificate in the exporting country. It is for a single product only since manufacturing arrangements and approved information for different dosage forms and different strengths can vary.*

[2] *Use, whenever possible, international nonproprietary names (INNs) or national nonproprietary names.*

[3] *The formula (complete composition) of the dosage form should be given on the certificate or be appended.*

[4] *Details of quantitative composition are preferred, but their provision is subject to the agreement of the product-license holder.*

[5] *When applicable, append details of any restriction applied to the sale, distribution, or administration of the product that is specified in the product license.*

[6] *Sections 2A and 2B are mutually exclusive.*

[7] *Indicate, when applicable, if the license is provisional or if the product has not yet been approved*

[8] *Specify whether the person responsible for placing the product on the market:*

(a) manufactures the dosage form;

(b) packages and/or labels a dosage form manufactured by an independent company; or

(c) is involved in none of the above.

[9] *This information can be provided only with the consent of the product-license holder or, in the case of non-registered products, the applicant. Non-completion of this section indicates that the party concerned has not agreed to inclusion of this information. It should be noted that information concerning the site of production is part of the product license. If the production site is changed, the license must be updated or it will cease to be valid.*

[10] *This refers to the document, prepared by some national regulatory authorities, that summarizes the technical basis on which the product has been licensed.*

[11] *This refers to product information approved by the competent national regulatory authority, such as a Summary of Product Characteristics (SPC).*

[12] *In this circumstance, permission for issuing the certificate is required from the product-license holder. This permission must be provided to the authority by the applicant.*

[13] *Please indicate the reason that the applicant has provided for not requesting registration:*

(a) The product has been developed exclusively for the treatment of conditions—particularly tropical diseases—not endemic in the country of export.

(b) The product has been reformulated with a view to improving its stability under tropical conditions.

(c) The product has been reformulated to exclude excipients not approved for use in pharmaceutical products in the country of import.

(d) The product has been reformulated to meet a different maximum dosage limit for an active ingredient.

(e) Any other reason, please specify.

[14] *Not applicable means that the manufacture is taking place in a country other than that issuing the product certificate and inspection is conducted under the aegis of the country of manufacture.*

[15] *The requirements for good practices in the manufacture and quality control of drugs referred to in the certificate are those included in the thirty-second report of the Expert Committee on Specifications for Pharmaceutical Preparations (WHO Technical Report Series, No. 823, 1992, Annex 1). Recommendations specifically applicable to biological products have been formulated by the WHO Expert Committee on Biological Standardization (WHO Technical Report Series, No. 822, 1992, Annex 1).*

[16] *This section is to be completed when the product-license holder or applicant conforms to status (b) or (c) as described in note 7 above. It is of particular importance when foreign contractors are involved in the manufacture of the product. In these circumstances the applicant should supply the certifying authority with information to identify the contracting parties responsible for each stage of manufacture of the finished dosage form, and the extent and nature of any controls exercised over each of these parties.*

Appendix 5: Summary Guide for Policymakers, Directors, and Managers

A. Introduction

Successful procurement and management of contraceptives, pharmaceuticals, and other commodities is crucial to the success of reproductive health (RH) programs, because they require uninterrupted supplies of safe, effective products. *Uninterrupted* is a key word for these products; to be effective and provide the required protection, they must be used regularly. Programs that cannot support the regular use of contraceptives do not achieve their objectives; they develop a poor reputation, and soon lose their clients.

Developing and transitional countries have a significant need for dependable RH services in the public sector; but, in these same countries, public sector procurement can be a challenging job, often encumbered by problems and delays that cause stockouts.

The environment—including laws and regulations, resources and infrastructure, routine practices of the government apparatus, and decisions made by those in authority—limits the skill and speed of the supply process.

Policymakers at every level have an impact, either positive or negative, on this all-important environment.

This summary is written for the following:

1. Policymakers who are part of larger government bodies and heads of ministries, or administrative units serving as legislative delegates; as well as higher-level government officials. This group may have little or no specific exposure to RH issues, in general, and the procurement of contraceptives and pharmaceuticals, in particular. They may not understand how the quality and timeliness of these products affect the *greater good* for the people they are pledged to serve.
2. Personnel who, on occasion, become involved in certain parts of the RH supply process—usually, the budgeting and financial aspects—but, may not be aware of RH supply goals, good public sector procurement practices, or operational details within their own systems that can affect the quality and timeliness of RH supplies.
3. Others may find this summary useful as a supplement to the detailed learning modules.

For convenience, the remainder of this summary guide will include all audiences under the general heading of *policymaker*.

The summary guide will help readers understand how to effectively support the primary goals of RH supply: *safety, efficacy, and timely delivery of the product.*

To achieve this objective, the guide addresses the following key topics:

- Identify where policymakers have an impact on RH supply.
- Identify what policymakers need to know about RH supply.
- Provide an overview of the RH supply process.
- Identify issues that lead to delays and other problems in the RH supply process.

A general understanding of pertinent processes and key issues will lead to beneficial decisions, or at least to decisions that are not harmful. The guide is also intended to present realistic expectations about RH supply matters.

B. Where Policymakers Have an Impact on Reproductive Health Supply

Following are some key areas where policymakers can have an impact on the overall effectiveness and efficiency of the RH supply process, either favorably or unfavorably, depending on the decisions they make:

- Drafting and enforcing public procurement laws and regulations, including anticorruption measures.
- Interpretation of policies on fair competition; for example, World Health Organization (WHO) pre-qualification as a QA measure is sometimes challenged inappropriately as limiting competition.
- Staffing policy can negatively impact personnel in procurement positions (e.g., routine rotations sometimes lead to untrained, inexperienced procurement personnel or personnel that lack specific knowledge required for RH product procurement).
- Budget allocations:
  - financing and support for staffing and internal infrastructure
  - financing for product procurement.
- Management of funds—allocated funds are sometimes unavailable when the obligation to the supplier must be paid.
- Efficient, timely decisionmaking and approval processes.
- Building reputations for trouble-free international commerce and fair competition, which attract good suppliers and increase competition.
- Taxation policy—must a program pay taxes on goods that will be used in the public sector?
- Regulatory and product licensing issues and procedures.
- Import procedures and restrictions.
- Disposal of expired or defective goods.
- Inspection and acceptance policy.
- Centralized versus decentralized procurement.

While usually left to the responsible program manager, other policymakers may play a part in decisions to—

- finalize quantification data
- determine the method mix for contraceptives
- allocate budgets and other resources
- add new products to the essential medicines list
- select the procurement option; e.g., procurement handled directly by staff or indirectly through an external organization
- assign procurement responsibility.

C. What Policymakers Need to Know About Reproductive Health Supply/Contraceptives

1. What are *reproductive health goods* and where do they originate?

WHO publishes *The Interagency List of Essential Medicines for Reproductive Health*, which includes the current international consensus on the rational selection of essential RH goods and medicines.[51] This list includes a wide range of pharmaceutical goods and medicines, from anesthetics and anti-infective medicines to disinfectants, contraceptives, and immunologicals, which have been selected for comprehensive reproductive health medical care.

For this summary guide, the list of RH goods and medicines focuses primarily on contraceptives, including hormonal contraceptives in pill or injectable form, intrauterine devices, implants, and condoms.

The technology required to produce contraceptives ranges from highly sophisticated steroid synthesis and compounding to factory floor injection molding and latex dipping—all very different manufacturing environments that require specialized, expensive equipment, and QC measures that often rule out local production in developing economies. Some of the pharmaceuticals are more likely to be produced locally in developing countries.

a. What does this means for the reproductive health supply system?

Most contraceptive purchases involve doing business with international manufacturers. This requires managing the transfer of funds through the international banking system and observing international trade conventions. It also includes widely recognized standards for public procurement, which potential suppliers expect. Import procedures and customs clearing systems are part of the process, as do licensing and regulatory issues. The supply process will be interrupted if any of these functions perform poorly.

2. What are the overarching requirements?

a. Quality

In purchasing products for the RH program, safety and efficacy are more important than cost. In this special area of health, a poor quality product can do irreparable harm; and, at the very least, waste public money by doing nothing. Unfortunately, unscrupulous sellers are in many countries; they sell fake, outdated, and substandard products to unsuspecting buyers at very low prices. In any situation, *bargain* prices are usually an indicator of poor-quality products.

For this reason, in all budgeting exercises for RH contraceptives, it is essential to incorporate measures that ensure the quality and efficacy of the product.

b. Timeliness

As explained earlier, RH programs must be able to support the regular use of contraceptives by their clients. The procurement process incorporates measures to promote timely, dependable re-supply; but, the outcome is unpredictable.

3. What are the implications for the quantity?

A single unit or even a month's worth of a contraceptive product is a minimal investment,

[51] World Health Organization (WHO) et. al. *The Interagency List of Essential Medicines for Reproductive Health.* Geneva: WHO; 2006. Available at: http://www.who.int/medicines/publications/Essential medicines/WHO-PSM-PAR-2006%20I_Rev.pdf.

but the annual quantity requirements for a target population are usually high.

a. What does this means for the reproductive health supply?

1) Potential suppliers can become aggressive when high values are at stake. They may attempt bribery or other corrupt practices; which, if successful, may drive away potential bidders in the next round of RH procurement. Unsuccessful competitors may try to subvert award decisions that are not in their favor—leading to long delays.

2) Rules for government and organizational spending are very stringent for high financial *thresholds,* which means the procurement process for contraceptives will probably be lengthy and complex.

4. What is the regulation of reproductive health goods by national regulatory authorities?

Regulatory licensing by national regulatory authorities (NRAs) is primarily a way to protect populations from unsafe, ineffective, poor quality; and costly contraceptives, drugs, and medical devices.

Worldwide, manufacturers of drugs and contraceptives must apply to local regulatory authorities for permission to market, or to distribute their products in a country, by submitting safety and efficacy data and samples. The local NRA reviews these data, does testing, and grants or refuses licensing in a process that is often time-consuming and expensive for the manufacturer. Therefore, licensing a product is usually not done unless the manufacturer is almost certain they will obtain a market share in the target country.

National customs services, in part, handle the enforcement of regulatory licensing. Unlicensed products are denied entry into a country, turned back, or quarantined; and eventually destroyed.

a. What does this means for the reproductive health supply?

Because most developing countries need to import contraceptives, local regulatory licensing is critical. Good public sector policy on competition requires the purchasing authority to accept bids from all potential suppliers, not just those offering already licensed products. If the bidder of an unregistered product wins the competition, the manufacturer of the offered product must obtain licensing (marketing authorization) from the local regulatory authority before a contract can become effective. The problem that arises is the length of time it takes for such licensing and whether or not it will delay delivery enough to impact the supply situation. Some governments deal with this problem at the policy level by approving a *fast-track* regulatory procedure that accepts evidence of licensing in countries with known stringent regulatory authorities, instead of prolonged and detailed investigations into the product's safety and efficacy by the local authority.[52]

5. What are the principles of good public sector procurement?

Good public sector procurement is based on competitive bidding and a fair, well-documented supplier selection process. Development banks and donors around the world, as well as many governments, require these widely held standards and procedures for entities using their funds. In the past, details have varied by institution; but, in recent years, the Organization for Economic Co-operation and Development has spearheaded a movement to harmonize rules, procedures, and documents across their membership. Health sector procurement involves additional product challenges. Products,

[52] For example, countries that are members of the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S) and the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) have known stringent regulatory authorities. For more information on the PIC/S and ICH, see Supplementary Topics, Section K: Regulatory Authorities.

such as contraceptives, pharmaceuticals, and vaccines have unique QA and regulatory requirements that are in addition to the normal provisions for public sector procurement.

6. Who works on reproductive health supply?

In a traditional setting, program personnel—usually with public health backgrounds—are responsible for program planning tasks; a separate procurement unit is responsible for procurement process tasks. In addition, critical contributors, such as the Ministry of Finance, pharmacy specialists, the RH unit, accounting, customs clearing, and central stores play peripheral, but important, roles.

It is not uncommon to see program management doing some of the procurement processing tasks and vice versa; the work can be divided in any way that fits the situation, if the assigned personnel have the appropriate skills and product knowledge.

7. How long should it take to purchase reproductive health goods?

Faster is not always better when it comes to quality and cost. It may take twelve months or more from the time funding is assured until the goods are delivered—even under a well-run international competition. The skill and diligence of the procuring entity are important factors in minimizing the time it takes to purchase RH goods, but there are other factors. The procuring entity cannot always control bottlenecks. For example, approvals may be delayed because a key individual is absent or distracted by other work.

8. How is the annual reproductive health goods requirement financed?

Funds for procuring RH contraceptives may come from a government's revenue budget; loans or grants from development banks (e.g., the World Bank); a bilateral donor arrangement; foundation gifts, etc. *Confirming the funding—regardless of the source—is the most critical link in the RH supply process*. In addition, the source of funding may dictate how the procurement should proceed, who should do it, and what markets can be solicited for offers. A government health program using its revenue funds may require its centralized national procuring entity to complete a competitive bidding process for its requirements.

D. Reproductive Health Supply Process

The RH supply process has three phases: (1) program planning, (2) procurement process, and (3) contract performance. Each phase comprises different elements. Table 13 visually represents the process.

Critical components link each stage in the supply process:

- funding
- signed contract
- payment guarantee
- delivery of high-quality products.

Failure at any critical link will terminate the supply process.

See the individual modules of the toolkit for additional details about the elements within each phase of the supply process, and the critical components linking each phase.

Table 13:

Three Phases	**Ten Elements**
1. Program planning	Defining reproductive health supply requirements
	Specifications
	Assessment of procurement options
	Budget, funding, and procurement requisition
Critical link: Funded procurement requisition	
2. Procurement process	Procurement planning
	Developing bidding documents and inviting offers
	Selecting suppliers
	Contracts
Critical link: Signed contract and payment guarantee	
3. Performance	Contract performance and monitoring
	Delivery of goods
Critical conclusion: Delivery and acceptance of high-quality products	

Phase I: Program Planning

The first time a new policymaker becomes aware of the RH supply program is often during the preparation and discussion of the annual budget. Budget requests for RH commodities are usually the result of a long, iterative process of planning and decisionmaking. The first part of the process is the requirements definition, followed by cost estimation; and, finally, establishing a budget requirement.

The modules addressing the elements of the program planning phase are as follows.

Element 1. Defining the Reproductive Health Supply Requirements

This is the process of selecting the appropriate products and forecasting the quantities to be purchased. These processes are based on program coverage goals, method mix, existing inventories, required delivery dates, and other program factors.

Element 2. Specifications

Technical specifications are one of the most important elements of procurement, because they—

- provide detailed information to suppliers about the goods to be purchased
- are the benchmarks against which the purchaser will judge the technical responsiveness of suppliers' bids.
- form the basis for the contractual obligation of the supplier to the purchaser
- are the criteria against which the purchaser will determine the acceptability of specific goods prepared by the supplier for shipment.

Specifications can be used to define a variety of areas, such as product information (quantity, size, color and registration), manufacturing requirements (standards for raw materials and cGMP's certification), testing requirements, and packaging and shipping requirements—all details that, when complete, ensure product quality and acceptability for the end user.

In addition to clear, accurate, and complete specifications, public sector procurement requires that specifications be prepared in a way that will encourage maximum competition. They must be *product neutral*. They must use generic terms, relative characteristics, and performance requirements instead of brand names and superficial descriptions. If cannot be avoided, the name must be followed by *or equivalent*. Requiring non-functional requirements—for example, color and exact dimensions—must have strong justification and may not be used to eliminate all but a specific brand.

A challenge and requirement at this phase is to ensure specifications are complete, comprehensive, and accurate, including obtaining input from all relevant governmental bodies, technical specialists, and program staff.

Element 3. Assessment of Procurement Options

Most organizations choose one of the following approaches when assessing their procurement options:

- Contract directly with a manufacturer (or its agent).
- Purchase goods from a distributor that has contracted with manufacturers for large quantities, which it resells.
- Hire a procurement agent to purchase goods on their behalf.

The choice directly affects cost, so it must be considered when developing a budget. Contracting directly with a manufacturer, or its agent, usually returns the lowest unit price, but requires the most expertise. The decision is made based on what is possible, what is practical, who can/will do the procurement work, and cost implications. In many cases, a program will use different options for different products. Program managers usually decide on the best course of action for their circumstances; however, organizational and government policies play a role.

The two main options, direct procurement and indirect procurement, and their variations are shown below. See exhibit S-1 for some of the requirements for each, plus financial commitments and risk factors.

Exhibit S-1: Procurement Options Table

Requirements and Results for the Reproductive Health Purchaser							
Procurement Option	Purchase Quantity	Foreign Exchange Required[1]	Procurement	Infrastructure[2]	Product cost	Fee[3]	Risk Level[4]
Direct international bid	Large	Yes	High	High	Low	No	Low
Direct international bid with private agent	Large	Yes	Med	Med	Med	Yes	Med
Indirect public procurement agency	Large	Yes	Low	Low	Med	Yes	Low
Indirect private procurement agency	Med to Large	Yes	Med	Med	High	Yes	Med
Indirect parastatal procurement service	Any	No	Low	Low	High	Yes	High
Indirect regional buying alliance	Any	Yes	Low	Med	Med	Yes	Med

[1] Required level of procurement skills needed to administer the procurement option

[2] Ministry of Health infrastructure required to support procurement

[3] Fee included in the cost

[4] Risk of a poor-quality product; risk level is based on product knowledge, skill of agent, and proper administration.

a. Direct Procurement

- international competition
- international competition using a private procurement agent
- sole-source procurement
- small-scale national competition.

b. Indirect Procurement

- international supply service
  - public sector agency (e.g., UNFPA, UNICEF)
  - private sector agency (e.g., IDA Foundation, Mission pharma)
- international procurement agency (the private-sector Crown Agents)
- parastatal procurement service
- regional buying alliance (where one exists).

Element 4. Budget, Funding, and Procurement Requisition

a. Cost Estimates

Cost estimates are not as clear as they might seem. Prices for each product vary widely, based on how the procurement is done (see the procurement options above) and the level of the supplier in the distribution chain. Moving down the distribution chain, from manufacturer to retail seller, adds costs and a profit margin at each level that is passed on to the purchaser. In addition, discounted public sector prices are available for some products from some international suppliers and manufacturers. Access to these special prices is usually tied to a country's gross national income (GNI), with the poorest countries paying the lowest prices. Large-quantity purchases often rate discounted pricing, as well. Thus, the lowest prices may be seen when a low GNI country purchases large quantities from a high level of the distribution chain. The GAVI Alliance provides support to national governments to procure discounted vaccines through the GAVI Fund. Eligibility is determined by national income; only countries with a GNI per capita of less than U.S.$1,000 in 2003 qualify. Currently, there are 72 eligible countries.[53]

b. Assessment of Supply Possibilities

To develop useful cost estimates, the procuring entity must determine the types of sellers available for each product. Supply possibilities depend on specific issues:

- access to convertible currency and banking for international purchases
- agreements with financing organizations
- national trade barriers
- regulatory constraints
- level the supplier is likely to be interested in, based on quantity requirements and expenditure levels.

c. Pricing Research

The procuring entity must also research current product pricing information and associated costs. The following resources can be used for this purpose:

- quantities and last prices paid
- direct inquiries to manufacturers
- published price guides
- United Nations agency pricing
- discounted pricing, if eligible (low GNI)
- associated costs, including—
  - taxes and fees
  - freight and insurance costs and modality of last shipments
  - inspection and testing
  - inland transport.

d. Calculating the Budget Requirement

The estimated cost to fulfill the coverage target is calculated by multiplying each item by its likely price and adding any associated costs. If the estimated cost is more than the amount likely to be available—as is often the case in developing countries—the RH program must adjust the number of clients it can serve, delay some of the procurement, and draw down on buffer stock (if any exists), or find additional funding. See module 4 for additional information on budgeting.

[53] For more information, see http://www.gavialliance.org/support/who/index.php

e. Procurement Requisition

After funding is assured, the program that needs the RH products can issue a procurement requisition to the entity responsible for procuring the goods by providing detailed information about product requirements by item, quantity, delivery date, and technical specifications.

Phase II: Procurement Process

Between funding a procurement request and signing a contract, many decisions must be made; this activity is usually called the *procurement process*.

Element 5. Procurement Planning

The procuring entity selects an appropriate method for purchasing the required goods if the method has not been specified by the financing organization in policies tied to financial thresholds. For contraceptives, the procurement method is usually international competitive bidding, either open to all or restricted to products and manufacturers that are prequalified in some way.

Procurement planning also establishes expectations for a delivery date, a time frame for payment, and a framework for monitoring progress.

Element 6. Developing Bidding Documents and Inviting Offers

Bidding documents have rules and conditions for bidding, state how a winning bidder will be chosen, and prescribes conditions of the resulting contract, including the method of payment. They also include formal specifications, quantity requirements, and a delivery schedule. Under good public sector procurement practice, everything must be clearly stated; nothing can be changed after the bids are opened; the process of developing bidding documents necessarily requires many careful decisions. At times, the procuring entity will need information or a decision from the policymaker level before it can proceed. Delays in obtaining information and decisions can easily mean a delayed procurement process and critical shortages in the supply chain. In addition, failure to incorporate product quality protection into bidding documents and subsequent contracts can result in the receipt of substandard products.

Most governments and organizations use model (standard) bidding documents with mandatory wording in line with official policy. clauses specific to the procurement are filled in by the procuring entity. Finished documents are often more than 50 pages long after all the necessary schedules and bidding forms have been included; often, they are difficult for casual readers to understand.

After the bidding documents have been prepared and approved, the procuring entity alerts potential suppliers about the opportunity to bid. This is done through advertisements in local and national publications, as well as on public access websites and bulletin boards. Sometimes trade organizations are also notified.

Bidding documents are numbered and sold, upon request, to potential bidders, at a nominal cost—enough to ensure that the party is actually interested in bidding, but not so much as to restrict competition. The purchasing office records contact information for everyone who receives bidding documents to ensure they can be notified in the event of amendments, special meetings, etc.

Offers—or bids—may start arriving shortly after bidding documents are made available and continue up until a pre-established closing date. However, these bids cannot be opened and must be securely stored until the time and place indicated in the bidding documents. At that time, they are opened in public,

often by a specially appointed bid opening committee. Basic, pertinent data, such as price, delivery date, and the bidder's name and country, are announced; but a winning bid is not identified at this time for two reasons: (1) price is rarely the only determinant in selecting a supplier, and (2) the prices indicated by bidders may not be fully comparable.

Element 7. Selecting Suppliers

In most public sector systems, suppliers are selected by special committees convened for that purpose and chaired by a relatively high-level official. Procurement personnel may help with the paperwork, but the committees are responsible for examining, evaluating, and comparing the offers; and finally agreeing on the best one. In public sector procurement, this is a strict process guided by evaluation criteria announced in the bidding documents in advance. International suppliers expect the selection process to adhere to the stated evaluation criteria, which means that problems are likely if the selection is based on ministerial privilege or anything other than the evaluation criteria.

After the best offer has been determined, the financial, commercial, and technical background of the apparent successful bidder (and one alternate) will usually be checked to ensure the company has the capacity and capability to follow through on the contract.

Approvals at higher levels of an organization or government are generally required before an actual award is made. Unfortunately, bottlenecks that delay the delivery schedule often happen at this step.

Element 8. Contracts

After the supplier has been selected, the contract needs to be prepared, signed, and awarded. Often, there is a time limit for obtaining signatures. This activity also includes deciding on payment methods.

The first responsibility for contract execution lies with the purchaser, which provides some type of payment guarantee to the supplier. Particularly in trade with developing countries, manufacturers usually do not enter an order into production until this payment guarantee is in place. Producers frequently have a backlog of orders for products in high demand (e.g., condoms), so quickly establishing the payment guarantee keeps the delivery date on track. The most prevalent guarantee is a commercial L/C, which the purchaser opens at a reputable international bank, in favor of the seller. The purchaser deposits money in the bank to *collateralize* the L/C; the bank holds it until the seller provides documentary evidence that it has complied with the terms and conditions of the L/C. See annexure 2 for more information about L/Cs and payment methods.

Phase III: Performance

In the performance phase of the RH supply process, the procuring entity monitors the supplier's performance, including arranging for pre-shipment inspection of contraceptives, customs clearance upon arrival at the port of entry, and delivery to the receiving warehouse.

Element 9. Contract Performance and Monitoring

Contracts for contraceptives may require independent inspection of the goods at the supplier's facility when they are ready for shipment. This helps ensure that incoming products are in good condition, packaged and labeled properly, and are supplied in the correct quantities. For condoms, a sample is drawn and sent to an independent laboratory for quality testing, as well. Condom testing discourages marginal suppliers from providing poor quality products that malfunction during use. For more

information, please refer to WHO's *The Male Latex Condom: Specification and Guidelines for Condom Procurement*[54] and to *Supplementary Topics, Section I: Product Inspection and Testing.*

One way contraceptive purchasers can enforce QA requirements is by requiring a Certificate of Clean Findings as part of the L/C evidence mentioned above. If the supplier cannot provide the required certificate for the bank, the bank will determine that it has not fulfilled the terms and conditions and will not release the payment.

Element 10. Delivery of Goods

Public sector contraceptives are normally shipped via ocean unless the supply source is close enough for trucking. Both options are far less expensive than air, which is usually reserved for emergency situations.

At the port of entry, goods are inspected for damage and, in the case of contraceptives and pharmaceuticals, their regulatory licensing status is appraised. The procuring entity may hire a customs clearance agent to carry out necessary paperwork and to obtain a release from customs. When this is not done within a few days, the port authority applies demurrage (storage) charges, which can add up to significant amounts.

On release from customs, the purchaser must transport the goods to its own warehouse. Some customs clearance agents will make this arrangement; sometimes a local representative of the supplier will do it. In most cases, the purchaser sends its own trucks or hires private transport.

After the goods are delivered to the initial warehouse, personnel conduct a receiving inspection, confirming that all goods are present according to the accompanying packing lists, are in good condition, and product names and expiry dates are clearly marked.

E. Issues that Create Significant Delays and Other Problems in the Supply Process

This section identifies some of the common problems that occur in the supply process that can delay procurement and create product stockouts. The toolkit module(s) where additional information can be found on ways to address each problem is noted in parentheses.

1. Government Policy versus Practical Application

a. Blanket policy devolving procurement to regional and local facilities
   - *Significance:* Centralized procurement is a better option for contraceptives because it offers economies of scale and allows for better management of national stocks. In addition, contraceptives (in program quantities) are usually imported, requiring skill and knowledge that is not commonly found below the central level.
   - *The result:* Contraceptives purchased at regional and local levels can be expensive and often out of stock because of weak management. RH program personnel may want to fight for centralized procurement of contraceptives as an exception to any blanket policy (decentralized supply is much more appropriate for pharmaceuticals, including those used in RH programs).

b. Procurement rules, policies, and standard bidding document clauses that fail to consider the special nature of contraceptives
   - *Significance:* Issues of concern when purchasing machinery and equipment (e.g., spare parts) do

[54] World Health Organization (WHO), United Nations Population Fund, Joint United Nations Program on HIV/AIDS. The Male Latex Condom: Specification and Guidelines for Condom Procurement. Geneva: WHO; 2003. Available at: http://www.who.int/reproductivehealth/publications/family_planning/9241591277/en/.

not apply to contraceptives and pharmaceuticals.
- *The result:* Contracts without appropriate quality protections; confusion and/or protest on the part of bidders, leading to delayed delivery or cancellation of the bid.

c. Government rules that limit financial transactions to the country's national bank
- *Significance:* It may be impossible to open a commercial L/C that will be honored in another country.
- *The result:* Cancellation of the contract because of lack of compliance by the purchaser.

d. Blanket government regulations prohibiting cash in advance as a payment modality
- *Significance:* The rule is not the same as the United Nations agency requirements.
- *The result:* Option of purchasing contraceptives through UNFPA is eliminated, unless a variance can be arranged (which usually takes a good amount of time).

e. Blanket taxation on imports
- *Significance:* Takes money from one government pocket (public health) and puts it into another (general fund).
- *The result:* The RH program can serve fewer clients.

f. Requiring that certain procurement-related activities be handled by a different ministry
- *Significance:* Once out of the hands of the procuring entity, it is impossible to control timing. To make sure the invitation reaches as many potential bidders as possible, the procuring entity uses websites, bulletin boards, and newspapers for the bid announcements.
- *The result:* It is almost impossible to comply with good public sector procurement policy that requires that all announcements of an opportunity to bid appear at the same time; bidders can lodge valid complaints that will probably delay the procurement process.

g. Mandatory bidding document clauses (approved at ministerial level) that do not represent normal operating procedures or the actual situation
- *Significance:* Requirements to perform in a certain way are part of the bidding documents.
- *The result:* Bidder protest and delayed procurement.

h. Government hierarchy, instead of familiarity with a specific bid requirement, determines the chairperson for pre-bid meeting
- *Significance:* The chairperson controlling the meeting is unlikely to understand pertinent issues or the subject of the procurement.
- *The result:* Unproductive and sometimes poorly run pre-bid meeting; legitimate questions not answered promptly; confusion among potential bidders; potential for delaying the procurement process.

2. Program-Level Decisions

a. Deciding to use a procurement agent without someone on staff who knows what the process should be
- Significance: Someone needs to monitor the agent's performance.
- The result: Potential for oversights; noncompliant processes; delays; less than the best supply contract; money wasted (fees payable to the agent).

b. Failure to consider warehouse capacity when scheduling shipments
- *Significance:* Inability to plan space for the shipments; creating a lost opportunity to solve problems before they occur.

- *The result:* Overcrowding or having to pay for additional space in another facility.

c. Accepting donations (or bargains) on goods that are not needed
   - *Significance:* Excess goods fill up warehouse space needed for other products.
   - *The result:* Overcrowding or having to pay for additional space in another facility.

d. Specifying and planning a delivery date without considering the normal timeline for procurement—12 months
   - *Significance:* False expectations.
   - *The result:* Potential for stockouts and no plan in place to cope with the realities of the stock situation; lost opportunity to prevent problems before they happen.

e. Failure to act on information and constraints uncovered during planning work that will affect what is possible and how long the supply process will take
   - *Significance:* Unrealistic expectations.
   - *The result:* Later deliveries; potential for stockouts.

3. Financial, Budgeting, and Accounting

f. Accounting system not showing outstanding commitments
   - *Significance:* Overstated line item balances.
   - *The result:* Some managers will use funds that will be needed later.

g. Manager's failure to consider a likely time frame for payment obligations (module 5)
   - *Significance:* Funds may not be available when payment obligations are due.
   - *The result:* Delayed delivery; cancelled contract.

h. Lack of provision for access to ready cash for minor expenses
   - *Significance:* Alternative arrangements will be needed for—
     - postage to send bidding documents to potential bidders located outside the immediate area of the procurement office
     - car fare to transport personnel on procurement-related business
     - minor expenses related to port clearing.
   - *The result:* Delays while alternative arrangements are being made will probably mean a later delivery (and in the case of port clearing, a risk of demurrage charges), incurring much higher costs.

i. Forgetting to add in associated costs and fees when developing a budget
   - *Significance:* Costs and fees must be paid whether they are budgeted or not.
   - *The result:* Not enough money to cover planned procurement; reduction in quantities/ shortages; using inappropriate prices for cost estimates; not understanding what is and is not included in representative prices.

j. Failure to provide for possible currency value fluctuation when budgeting for goods that will probably come from a foreign source
   - *Significance:* Potential for increased cost.
   - *The result:* Not enough money to cover entire commodity requirement; reduction in quantities/shortages.

k. Funding released quarterly or monthly
   - *Significance:* Funds must be accumulated in anticipation of future payment obligations. Requires

very careful timing of procurement activity so contract signing does not occur before enough money is available to cover the payment guarantee.
- *The result:* Potential for delayed delivery and stock shortages.

4. Bidding Documents

l. Not including special handling requirements in contracts and shipping instructions
- *Significance:* Goods may end up on an unprotected deck of a cargo ship in rough waters.
- *The result:* Heat and moisture can damage oral contraceptives, condoms, etc.

m. Lack of marking instructions for intermediate boxes
- *Significance:* Name of product and expiry date may be missing from cartons.
- *The result:* Inefficient storage and stock handling; incorrect items delivered to service sites.

n. Bidding documents not listing exactly what will be required for entry into the purchaser's country
- *Significance:* If proper documentation is not presented, shipment can be held at the port, returned, or destroyed.
- *The result:* Stockouts—a good example of how a small oversight in bidding documents can become a supply disaster.

o. Last minute edits to a bidding document clause that are not carried through to the corresponding clauses in other sections
- *Significance:* Can change intended meaning.
- *The result:* Confusion; need to amend bidding documents and/or extend the closing date; later deliveries.

p. Bidding document clauses that include commitments the procuring entity is not allowed to make and cannot support (sometimes seen with regulatory licensing)
- *Significance:* Bidders have false expectations.
- *The result:* Confusion; protest; later deliveries.

q. Bidding documents that require samples of pharmaceuticals and contraceptives be submitted with bids
- *Significance:* Products to examine and test at extra time and cost.
- *The result:* Samples of these products will not be representative of quality at a future point in time; however, a simple visual inspection can eliminate potential suppliers that submit obviously inferior products (e.g., in oily or dirty packaging).

5. Interministerial/Interdepartmental Coordination

r. Lack of a defined chain of authority
- *Significance:* Procurement personnel need to know where to look for decisions and advice.
- *The result:* Delayed production of bidding documents, etc.; later delivery dates.

s. Slow approvals
- *Significance:* Procurement process cannot advance without required approvals.
- *The result:* Offers may expire while waiting for approval; extensions must be arranged, and the whole procurement process will be delayed, leading to later delivery and possible stockouts.

t. L/C copies not made available to procurement staff by the finance unit
- *Significance:* Omissions or mistakes on the L/C not detected and corrected.
- *The result:* Later correction costly; L/C may not be useful to ensure product quality.

u. Government "short list" (of service providers) does not include appropriate contraceptive inspection and testing firms
   - *Significance:* Separate, lengthy bid process is required to establish them.
   - *The result:* Delayed supply process; lack of authorization to contract for associated services, such as inspection and testing.

v. Minimal advertisement of the invitation for bids
   - *Significance:* Potential bidders are not aware of the opportunity so there is not enough competition to validate the bidding.
   - *The result:* Bidding exercise may need to be cancelled and rerun, leading to later deliveries; potential for stockouts.

6. Evaluation Committees

w. Failure to check the references of the apparent winning bidder
   - *Significance:* Information provided by the bidder may not be completely truthful.
   - *The result:* Possibility that the supplier will not perform adequately; late deliveries; poor quality.

x. Lack of knowledge about how to read bidding documents
   - *Significance:* Bidding documents contain all requirements about the goods, the bidder's eligibility and qualifications, and describe how evaluation and selection will take place.
   - *The result:* Faulty interpretation leading to erroneous judgment and potential protests lodged by unsuccessful bidders; delayed procurement; possible cancellation of the bid.

y. Misunderstandings about interpreting common phrases used in procurement
   - *Significance:* Used to decide if the bidder is qualified to perform the contract.
   - *The result:* Potential error in selecting the winning bid; erroneous award; potential protests lodged by unsuccessful bidders; delayed procurement; possible cancellation of the bid.

z. Delay in identifying a winning bid
   - *Significance:* Bidders will need to be asked to extend the expiry date of their offers and bid securities; negative impact on the timeline.
   - *The result:* Later delivery; risk of stockouts; poor reputation for the next round of bidding.

7. Stakeholder Perception

aa. Misunderstanding the time frame required for procurement
   - *Significance:* Stakeholders often have some position of power as funders and contributors to RH programs, so their opinions matter.
   - *The result:* Negative impact on public procurement; unnecessary time and energy spent on helping peripheral individuals understand that public procurement requires at least 12 months from initiation to delivery and that *fault* cannot be tied to the efforts of any single office, as many players and situations have parts to play (the procurement staff itself cannot control, for example, how long an approval at the ministerial level might take).

F. Summary of Challenges

Policymakers should be aware of these challenges and do everything in their power to create policies that will overcome them. The following summarizes the key challenges found in each of the 10 elements of the RH supply process.

1. Defining reproductive health supply requirements

- Ensuring the quality of the information gathered and the forecasts generated.
- The budget available for contraceptive procurement often drives procurement, rather than the other way around.

2. Specifications

- Obtaining or crafting comprehensive specifications in the format and technical language of the relevant industry (e.g., contraceptives, pharmaceuticals, condoms).
- Providing a clear, correct description of all regulatory requirements, including those of the relevant NRA.
- Ensuring that technical specifications are product-neutral by using generic terms and relative characteristics.

3. Assessment of procurement options

- Understanding the options for procurement and the implications of each option.
- Honestly appraising the capabilities and environment of each option, even if findings are politically unflattering.

4. Budget, funding, and procurement requisition

- Developing reasonably accurate cost estimates for each item.
- Maintaining principles of good public sector procurement.

5. Procurement planning

- Recognizing and working around potential conflicts and constraints in the environment or system.
- Determining how long each step in the procurement cycle will probably take.
- Coordinating the procurement schedule with funds-release dates.
- Coordinating delivery dates with warehouse capacity and inventory requirements.

6. Developing bidding documents and inviting offers

- Building adequate product quality protections into the bidding documents.
- Neutralizing potential problems by using appropriate bidding document clauses.
- Ensuring that what the bidding documents say is what will actually happen, thus reducing the chance of bidder protest, which can lead to delayed delivery.

7. Selecting suppliers

- Maintaining principles and procedures of good public sector procurement: fair appraisal and evaluation of each offer, equitable comparison of all offers, and selection based on the lowest evaluated cost.
- Ensuring appropriate documentation and justification for selection and award.
- Ensuring that approvals are rendered without undue delay.

8. Contracts

- Ensuring that contracts contain the provisions necessary to obtain good quality products and provide adequate protection against a supplier's lack of performance.
- Ensuring timely contract award.
- Ensuring timely contract payment arrangements.

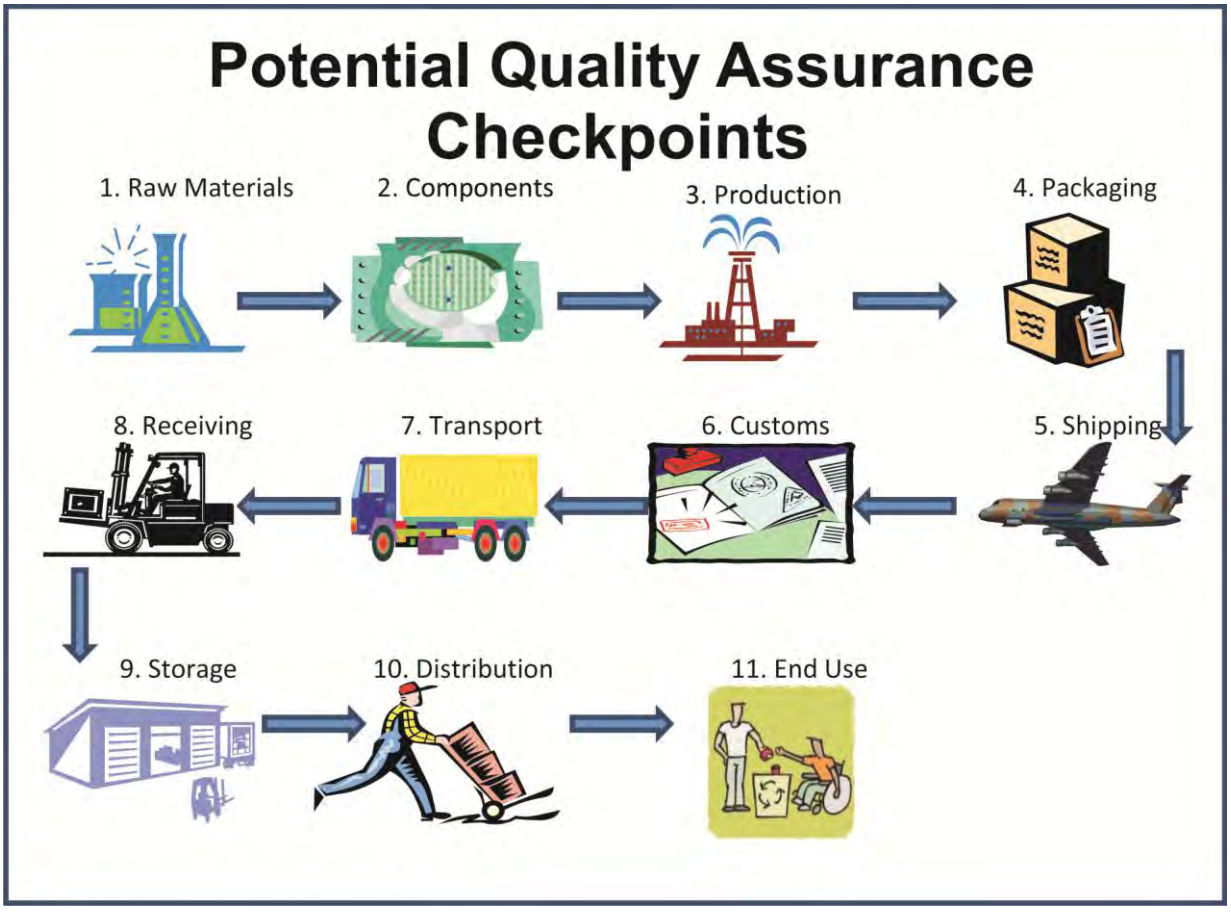
9. Contract performance and monitoring

- Eliciting supplier commitment to take contract compliance and monitoring seriously.
- Proactively implementing contract performance monitoring by the purchaser.

10. Delivery of goods

- Understanding and supporting customs clearance requirements so that the clearance process is completed in a timely manner.
- Ensuring proper inspection of goods upon receipt at the receiving warehouse.

Appendix 6: Product Quality Assurance



This figure is a visual overview of the key activities that occur in the standard product supply chain. The overall life cycle of a medicine has several points where quality needs to be built in—from manufacturing to distribution. The figure illustrates several activities in the product supply chain. Each point has the potential for quality risks:

1. **Raw materials and components:** Poor quality or counterfeit raw materials, substandard components.

2. **Manufacturing:** Absence or problems with active ingredients; cross-contamination of other products made on same manufacturing line.

3. Packaging: Substandard packing materials that do not adequately protect; improper labeling on primary packages.

4. Shipping: Temperature-sensitive products not shipped in proper environment (e.g., vaccines in cold chain).

5. Customs: Product not registered; missing or inconsistent documentation causing delays in clearance

6. **Receiving:** Product not inspected for damage upon receipt; product not recorded properly in receipt log book.

7. Storage: Product not stored in required environment; expiration date not monitored.

8. End use: Dispenser does not provide proper use and storage instructions; patient does not store product in required conditions.

Quality is ensured in the supply chain by the following key items:

- raw materials suppliers
- manufacturers
- national regulatory authorities
- procurement units
- logistics systems
- service providers and end users.

No individual agency has the sole responsibility for ensuring product quality through the life cycle of a product. Quality is ensured by collective and responsible action from each person throughout the supply chain. The roles and responsibilities of each person to ensure product quality are described below.

1. Role of the Raw Materials Suppliers and the Manufacturer

Raw materials suppliers are responsible for identifying manufacturing requirements and control specifications to ensure that products can consistently be produced in accordance with these requirements. A supplier must adhere to international pharmacopoeia standards; and must also conduct the necessary tests and sampling to demonstrate that a product is safe, effective for its intended use, and of good quality. Additionally, a raw materials supplier must certify the safety, efficacy, and stability of the finished raw materials; and maintain the necessary drug master files and monographs of the active pharmaceutical ingredients.

The manufacturer is responsible for ensuring that pharmaceutical products are suitable for their intended use and comply with applicable national or international standards and purchase contract specifications. It is the manufacturer's further responsibility not to place users at risk due to inadequate safety, quality, or efficacy. Throughout the production process, manufacturers must adhere to GMPs. As part of the GMPs, manufacturers should validate all raw materials and suppliers to ensure that starting materials meet production specifications. In particular, a manufacturer should have an independent QC unit that monitors the quality of incoming materials, quality of the product at key stages in the production process, and the quality of the finished products. Manufacturers also must monitor product stability to ensure that products do not deteriorate before the marked expiry date.

2. Role of the National Drug and Medical Device Regulatory Authority

Establishing a national drug and medical device regulatory authority is an important element of a national drug policy, particularly in developing countries; because it is the basis for product licensing, which ensures the quality of both imported and domestically produced products. A comprehensive registration or licensing system should include mechanisms for independent product evaluation;

including inspection and monitoring of manufacturing facilities, as well as testing and inspection of finished products. Drug regulatory authorities should have the authority to recommend and enforce corrective actions, when necessary.

The degree of development of drug regulatory authority varies considerably among countries, ranging from those with limited capacity (i.e., no up-to-date legislation or regulation) to those considered stringent authorities with comprehensive drug regulatory capacity—including, for example, product registration, licensing for manufacture or distribution, and a full range of QC testing. For more about countries with stringent authorities, see *Supplementary Topics, Section I: Regulatory Authorization*. These differences notwithstanding, the standard of control varies from country to country and even among comparable systems. In some exporting countries, drugs are registered and sold freely, but not rigorously evaluated for efficacy. In other countries, manufacturers may produce exclusively for export; the exporting country's drug regulatory authority may not closely scrutinize these manufacturing facilities. Procurement offices still need to request certificates from the drug regulatory authorities of the exporting country, as recommended by the World Health Organization (WHO).

3. Role of the Logistics System

An RH program's logistics management system has the primary role to assist in ensuring product quality from the time the product clears customs until the time it reaches the user. The logistics system is responsible for ensuring that products are transported and stored correctly and that practices such as first-to-expire, first-out are routinely used in distribution. Products must be stored that ensures their quality and integrity and that batch traceability is maintained. All logistics systems should have mechanisms for monitoring product quality upon receipt, at regular intervals during storage, and for documenting and reporting results.

4. Role of the Service Provider and End User

Service providers and users also play an important role in ensuring product quality and effectiveness. Providers should store products according to the manufacturer's directions and should check the expiry date, integrity of the packaging, and any other signs of possible deterioration of the product before distribution to users. Users should also be familiar with the expiration date and package integrity of all products before use. Users should report any adverse reactions to the provider; who, in turn, should report them to the logistics manager, clinical manager of the program, or other individual, depending on the nature of the complaint and the established reporting procedures.

To help the key staff better manage their processes for ensuring quality, several international standards and norms have been developed. These standards and norms establish specific procedures and practices that to support a consistent approach to implementing operational activities to mitigate inherent risks to product quality.

- **Good laboratory practices** (GLP) are a set of principles that provide a framework within which laboratory studies are planned, performed, monitored, recorded, reported, and archived.
- **Good dispensing practices** confirm the authenticity of the product, inspect the package and product, and ensure storage of the product under the required conditions.
- **The International Standards Organization** (ISO) develops standards that are a broad umbrella for quality systems; ISO 9001 outlines criteria for a quality management system. ISO 13485 is a version specifically for medical devices. ISO standards also call out product-specific standards, such as ISO 4074, which specifies condom requirements and testing standards. However, one must be cautious when considering certification of compliance with ISO 9001 because the certification

process is conducted by groups with varying levels of capacity and technical competence.

- **The CE mark** is a mandatory European marking for certain product groups to indicate conformity with the essential health and safety requirements set out in European Directives for the European Economic Area. For a product to use a CE mark, the item must have documented proof that it meets the relevant requirements. Sometimes, this is achieved using an external test house that evaluates the product and its documentation. Often, it is achieved by the company's internal self-certification process.

5. Role of the Procurement Unit

The critical role of the procurement process in obtaining quality products cannot be overemphasized. The procurement agency must be able to ensure that the products are safe and effective, and that it has maximized supplier selection and assessed its own capacity to judge these requirements. The procurement agency must maintain a comprehensive documentation infrastructure that includes policies, guidelines, norms, standards, manuals, procedures, records, and related documents.

Initially, the ideal way to ensure quality products is to only buy from WHO or UNFPA pre-qualified manufacturers, or from manufacturers whose products are registered by a Stringent Regulatory Authority. (For more information on pre-qualification, see appendix 6: Pre-Qualification). However, if this is impossible, the purchaser should take the following steps:

- *First***:** Know the best available product standards. Check with the local regulatory authority to identify registered products and national standards. If these are not available, check with other regulatory authorities or international standards bodies, such as ISO. Ensure that the products specified comply with country legislation on registration licensing status and patent registration or restrictions.
- *Second*: Know the marketplace and the available manufacturers. The purchaser must ensure that the product can be traced to the finished product manufacturer, and the manufacturer can trace the product ingredients to their producers. Understand the capacity of the supplier's plant(s). Evaluate the qualifications of key production and QC personnel. Investigate how the supplier is regarded by knowledgeable physicians and pharmacists. Review any internationally recognized certificates that the manufacturer holds (e.g., ISO). Review any information available from public sources—such as newspapers or trade journals—concerning the supplier's performance locally or in other countries.

Check to see if the supplier is registered in an ICH or PIC/S country, if the product is registered for export only, and if the product is registered in the country of the purchaser. Contact the national regulatory authority to establish what types of inspections are performed at the manufacturing site and what medicines are QC-tested for analytical verification of quality; levels and types of inspections, if any, can vary from country to country. Review the results of the most recent inspections and inquire about recall history. Review certification documents that are available from the regulatory agency concerning the supplier's status and compliance with current GMP.

Buyers with pharmaceutical staff trained in GMP inspection, or who hire a consultant with this expertise, can perform their own inspections of manufacturers that are potential suppliers if funds are available to do this. In any case, the purchaser should always reserve the right to inspect the manufacturing facility. Request references from the supplier and check them, especially ask for any concerns or episodes of quality problems.

- *Third:* Work with the pharmacy staff to develop and articulate appropriate quality indicators and

quality conformance requirements that will be used as part of the product and contract specification. One possible requirement may be to review manufacturer documents, such as batch certificates of analysis, sterility, or others, as applicable. Another may be to conduct pre-shipment testing by an independent, credible international laboratory (also see Element 9: Contract Performance and Monitoring). Include penalties in the contract for failure to comply with the stated quality indicators.

- *Fourth:* Ensure that the product specifications are brand neutral. Beware of specifications that pertain to only one manufacturer's product.
- *Fifth:* Upon arrival of the goods, visually inspect the products to make sure that they comply with labeling and packaging requirements, and that the correct goods and quantities were received.

By implementing the above practices the procurement unit will help to ensure that only contraceptive products of good quality are procured and supplied to the Government of Pakistan's family planning programs.

Note: Above information provided *from Procurement Capacity Toolkit: Tools and Resources for Procurement of Reproductive Health Supplies*. PATH. 2009.

Appendix 7: Pre-Qualification

This appendix contains information about—

A. Pre-qualification Issues
B. Stringent Regulatory Authorities
C. World Health Organization Pre-qualification
D. Pre-qualification Documents

A. Pre-Qualification Issues

Procuring entities sometimes limit competition for contract awards to a list of potential bidders and products they have pre-screened and approved through a pre-qualification process. This involves advertising the opportunity to pre-qualify and providing a set of documents to applicants that establish the rules and requirements, as well as evaluating every application. In addition, WHO's Prequalification of Medicines Program provides a list of pre-qualified products and manufacturers. WHO's pre-qualification program is described in more detail in section 2 of this appendix.

Pre-qualification focuses on two separate aspects of the selection process:

- quality, safety, and efficacy of the *product*
- reliability of the *supplier*.

In countries with weak regulatory systems, pre-qualification can be a valuable tool for ensuring product quality, as well as the reliability of the supplier. In countries with satisfactory regulatory systems, pre-qualification tends to focus more on supplier reliability.

Pre-qualification can be an attractive time-saver in situations when a large number of bids from questionable sources are routinely received. It may be less desirable for procurement that attracts bids from smaller, better regulated markets.

Curative pharmaceuticals are produced by many manufacturing firms in nearly every country in the world; open bids can result in an excess of questionable offers. In small countries with weak regulatory systems, pre-qualification can be used to develop a core of reliable suppliers of quality products from which to draw repeatedly.

The hormonal contraceptive marketplace is much smaller than the general pharmaceutical marketplace; it is dominated by products that have been licensed by stringent regulatory authorities, such as those belonging to the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme and the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use. In addition, WHO recently added hormonal contraceptives to its prequalification project; and they will soon include on their website lists of products they have investigated and accepted. Thus, the reliability of the supplier, rather than the quality of the product, would be the most likely focus for pre-qualification.

The *condom marketplace* is not large compared to general pharmaceuticals, but it has a history of quality issues. Condom production comes from a non-pharmaceutical environment; until the 1990s, many NRAs did not regulate or license this product. In 1989, WHO began providing guidance for condom

purchasers. The most recent WHO guidance on condom procurement can be found in the document, The Male Latex Condom: Specification and Guidelines for Condom Procurement (WHO 2003). The United Nations Population Fund (UNFPA) employs a pre-qualification program for condom manufacturers; they only procure condoms from manufacturers that meet the pre-qualification requirements. UNFPA is collaborating with WHO to harmonize the UNFPA pre-qualification process for condoms and intrauterine devices with WHO's pre-qualification process for medicines. Updated specifications and guidelines for procurement of these two contraceptives will be posted on the WHO and UNFPA websites when they are complete. The application of solid specifications and the use of pre-qualification systems have improved the quality of condoms during the past 15 years.

RH purchasers should consider their product profiles, availability of suppliers prequalified by WHO, size of the marketplace, and their own objectives in deciding whether or not to prequalify suppliers.

B. Stringent Regulatory Authorities

Another option available to help ensure quality products is to procure contraceptives that are approved and registered by countries with a stringent regulatory authority. This is defined as a national regulatory authority that participates in the International Conference on Harmonization (ICH) or the Pharmaceutical Inspection Convention and Cooperation Scheme (PIC/S). A description of both organizations, and a list of their member countries, is provided below. Limiting procurement of contraceptives to manufacturers whose contraceptives are manufactured and registered in a country belonging to one of these agencies can also be another way to pre-qualify a product.

International Conference on Harmonization

The International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) is a unique project that brings together the regulatory authorities and pharmaceutical industry experts of Europe, Japan, and the United States to discuss scientific and technical aspects of product registration. The purpose is to make recommendations on ways to achieve greater harmonization in the interpretation and application of technical guidelines and requirements for product registration in order to reduce or obviate the need to duplicate the testing carried out during the research and development of new medicines. This harmonization facilitates more economical use of human, animal, and material resources; and, to eliminate unnecessary delay in the global development and availability of new medicines; while maintaining safeguards on quality, safety, efficacy, and regulatory obligations to protect public health.

ICH Participating Regulatory Authorities (www.ich.org)

- European Union*
- Japan
- United States.

* Members include: Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Poland, Slovakia, Slovenia, Spain, Sweden, the Netherland,s and the United Kingdom

Pharmaceutical Inspection Convention and Co-Operation Scheme

The Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (jointly referred to as PIC/S) are two international instruments between countries and pharmaceutical inspection authorities. Together, they facilitate active and constructive cooperation in GMP. PIC/S's stated mission is "to lead the international development, implementation, and maintenance of harmonized Good Manufacturing Practice (GMP) standards and quality systems of inspectorates in the field of medicinal products." This will be achieved by developing and promoting harmonized GMP

standards and guidance documents; training competent authorities, especially inspectors; assessing (and reassessing) inspectorates; and facilitating the cooperation and networking for competent authorities and international organizations.

PIC/S Participating Regulatory Authorities (www.picscheme.org)

- Australia, Austria, Belgium, Canada, Czech Republic, Denmark, Finland, France
- Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein
- Malaysia, Netherlands, Norway, Poland, Portugal, Romania, Singapore, Slovak Republic
- Spain, Sweden, Switzerland, South Africa, United Kingdom.

C. World Health Organization Pre-Qualification

WHO has pre-qualification programs for vaccines, diagnostics, medical devices, and medicines. Reproductive health products are included in the medicines program. The WHO prequalification of medicines program results in a list of prequalified products and manufacturers that comply with unified international standards. The guiding principles of the pre-qualification process require that it be—

- **Voluntary:** Manufacturers can freely choose to participate or not to participate; however, countries will be increasingly required to use the WHO pre-qualification process for procurement of donor-funded products, because donors are increasingly requiring it—for example, the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM) and other agencies within the Reproductive Health Supplies Coalition.[55]
- **Legitimate:** The general procedures and standards for pre-qualification are reviewed and approved by the WHO expert committee system, which includes all WHO member states and governing bodies.
- **Endorsement:** The pre-qualification system was presented to and supported by the 10th and 11th International Conference of Drug Regulatory Authorities (ICDRA) meetings in 2002 and 2004. ICDRA is a forum for drug regulatory authorities of WHO member states that strengthens collaboration and identifies priorities for the regulation of medicines.
- **Transparent:** All information from the pre-qualification process is available on the WHO pre-qualification website. The pre-qualification process for medicines and devices is open to both innovator (patented) products and generic products. For pre-qualification to work, multiple manufacturers must participate. The WHO pre-qualification program is efficient in recognizing that some medicines have been through rigorous regulatory testing by credible agencies.
- **Capacity strengthening:** The pre-qualification process helps manufacturers strengthen their capacity. If a manufacturer does not initially meet the standards, it receives a specific report of findings and recommendations for improvements. Pre-qualification is not a strict pass/fail process. Manufacturers can make improvements and correct deficiencies, and then resubmit and continue to pursue pre-qualification.

Roles and responsibilities in the WHO pre-qualification process are divided as follows:

- WHO provides technical support, scientific support, and a guarantee that international norms and standards are incorporated and adhered to throughout the entire pre-qualification process—including assessment, inspection, and QC.
- For medicines, the assessment of dossiers and inspection of manufacturing sites are primarily done

[55] The Reproductive Health Supplies Coalition is a global partnership of public, private and non-governmental organizations dedicated to ensuring that all people in low- and middle-income countries can access and use affordable, high-quality supplies to ensure their better reproductive health. For more information, see http://www.rhsupplies.org/.

by qualified personnel, appointed by WHO, from the national regulatory authorities of the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S, http://www.picscheme.org) and the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH, http://www.ich.org) member countries. (For more information on the PIC/S and ICH, see section I: Product Inspection and Testing and section K: Regulatory Authorities.) WHO also arranges for site inspection of manufacturers to assess compliance with current cGMPs. A representative of the national regulatory authority traditionally accompanies the inspection team for the site inspection.

- Condom and intrauterine device pre-qualification is overseen and implemented by the United Nations Population Fund, on behalf of WHO; it is supported by independent technical experts with in-depth knowledge and expertise in the manufacturing and QA issues related to these products.

WHO pre-qualification systems cover these QA activities:

- Development, establishment, and promotion of norms and international standards to ensure safety and QA for products.
- Assistance to countries in building national regulatory capacity through networking, training, and information sharing.
- Provision of expertise and technical assistance through various activities in QA, regulation and legislation, safety, and efficacy.
- Provision of guidance in regulation, safety, and QA.
- Assessment of data from manufacturers regarding the quality, safety, and efficacy of their products; including details about the purity of all ingredients used in manufacturing, data about the finished products (such as information about stability) and the results of in vivo bioequivalence tests (clinical trials conducted in healthy volunteers).
- Performance of inspections at the manufacturing sites and assessment of working procedures for compliance with WHO cGMPs.
- Shipment of products to professional control testing laboratories for analytical verification of quality.
- Re-qualification of all medicines after one to three years and, at a minimum, every five years.
- Performance of random QC testing of pre-qualified medicines that have been supplied to countries.
- Investigation and resolution of complaints.
- Monitoring of supplier quality and taking corrective action if standards are not maintained.

D. Pre-Qualification Documents

Two different sets of pre-qualification documents available on organizational websites are listed in section I.3. One focuses on product quality, the other on supplier reliability.

- *Quality focus:* Practical Guidelines on Pharmaceutical Procurement for Countries with Small Procurement Agencies; Attachment 1: Model Questionnaire for Pre-qualification of Suppliers (WHO Regional Office for the Western Pacific 2002) (section I.3.b).
- *Reliability focus:* Standard Prequalification Document: Procurement of Health Sector Goods, Trial Edition (World Bank 2002) (section I.3.a).[56]

[56] Also see the "*Bidder Information Form" in the World Bank's Standard Bidding Document: Procurement of Health Sector Goods*

Appendix 8: Pre-Shipment Compliance Programs

This appendix contains information about—

A. Pre-Shipment Compliance Programs - General

B. Sample Compliance Program (OCs, Injectables)

C. Sample Inspection Order

D. Visual Inspection Review Guidelines

E. ISO 2859-1 - Relevant Tables

A. Pre-Shipment Compliance Programs - General

1.1.1.1 Pre-shipment compliance programs are used to assure the purchaser that goods made ready for shipment by the seller will meet all expectations of quality and safety, as well as other contractual requirements. Used in conjunction with a L/C, they are an especially effective means of contract enforcement because payment can be withheld until the seller presents documentary proof of compliance to a designated bank.

Pre-shipment compliance programs include inspection of the product at the manufacturer's facility before shipment. They may be limited to visual examination of the products, packaging, packing, labeling and markings, and QA documents; or, they may include drawing samples and sending them out for laboratory testing by an independent third party to verify quality, formulation, strength, dimensions, and other characteristics.

Different products and different situations call for different levels of pre-shipment compliance activity and, in some instances, none at all. Pharmaceutical products (including oral and injectable contraceptives) and IUDs purchased directly from well-known, reputable manufacturers in industrialized countries (U.S., European Union [EU], Japan, Canada, Australia, Switzerland, etc.) generally do not require this additional assurance of quality because they are licensed and monitored under the auspices of very strong national regulatory authorities. However, manufacturers can be asked to provide appropriate certification of laboratory testing.

Condoms are a different case because they are not regulated by pharmaceutical codes, but as medical devices; and, sometimes, they are not regulated. The manufacture of condoms is complex and can be influenced by a variety of different manufacturing and raw material factors—including seasonal weather patterns at the plantation where the latex raw material originated and dust in the manufacturing facility. Even when manufactured under a strict quality management system, a uniformly high-quality product cannot be guarantee: a small number of condoms in any lot may be defective and there is always a risk that quality may vary between production runs. When condoms are not manufactured under strict QC, the risk of poor quality product increases dramatically. In addition, unscrupulous manufacturers have been known to manipulate the sensitivity of their *100% electronic testing* equipment. Thus, for the purchaser, stringent pre-shipment compliance procedures are necessary. WHO has

published a set of specifications and guidelines[1] for condom procurement designed to help "ensure the highest level of safety consistent with high volume purchases, the needs of different populations, harsh environmental conditions and the probability of less than ideal storage conditions." These specifications and guidelines include a detailed pre-shipment compliance program of inspection and testing.

In summary, condoms always require pre-shipment inspection and testing, regardless of their origin; pharmaceuticals (including oral and injectable contraceptives) and IUDs require a pre-shipment compliance assessment if they originate in countries other than those with strong, recognized national regulatory authorities—the U.S., EU, Japan, Canada, Australia, Switzerland, etc.

The recommended content of a pre-shipment compliance program varies according to the product; condoms require the most stringent examination.

Condoms	Inspection, sampling, and testing of an entire statistical sample[57] from each manufacturing lot (usually 200–315 samples).
Oral contraceptives and emergency contraceptive pills	Inspection and sampling of each manufacturing lot; review of the manufacturer's quality certification; testing of five samples from each lot for the first three shipments from each manufacturer.
Injectable contraceptives	Same procedure as oral contraceptives except 20 samples should be tested.
IUDs	Same procedure as oral contraceptives, except testing should be done on the entire statistical sample. The number of samples depends on the lot size (50–100 samples is a reasonable estimate). A specialized laboratory is required. IUDs are medical devices, but regulated as drugs in some cases because of bioactive copper content. Dimensionality, flexibility, copper purity, and the quality/chemistry of polyethylene raw material are all issues.
Implants	Inspection and sampling of each manufacturing lot; review of the manufacturer's quality certification; testing of five samples from each lot for first three shipments from each manufacturer. In addition dimensionality, flexibility, impurity, and the quality/chemistry of polyethylene raw material are all issues.

1. Inspection

Inspection criteria must outline exactly what is to be examined and what constitutes compliance. The sample inspection order at the end of module 5, and the copy located at letter B of this appendix may be modified and used for inspection of packing, marking, and documentation for any product. In addition to a visual scrutiny of the product, the packing, and the marking, it directs the inspector to examine the documentation of the manufacturer's test results to confirm that values for

[57] The Male Latex Condom - Specification and Guidelines for Condom Procurement

the lot(s) prepared for shipment are within the range stated in the product's NRA dossier and/or specified in the relevant pharmacopoeia or standard. In the case of condoms, the procuring entity should refer to the WHO specification and guideline.

In cases where testing will be required, the procuring entity should add an instruction for the inspector to prepare the required number of samples and transmit them to a specified laboratory.

Pre-shipment inspection of the documentation and physical characteristics of most consignments typically costs under $1,000. However, rates vary and are usually based on the inspector's time and travel distance, so always obtain firm quotations.

The following organizations offer pre-shipment inspection and sampling services:

Partial List of International Inspection Agents	
FRANCE Bureau Veritas 67/71, boulevard du Château - 92200 Neuilly-sur-Seine - France Tel: +33 (0) 1 55 24 70 00 Fax: +33 (0) 1 55 24 70 01	SWITZERLAND Societe Generale de Surveillance SA Consumer Products Department 1, Place des Alps CH-1211 Geneva 1, Switzerland Tel. +41-22-739 9111 Fax. +41-22-731 1666
UNITED KINGDOM Crown Agents St Nicholas House, St Nicholas Road Sutton, Surrey SM1 1EL United Kingdom Tel. +44 (020) 8643 3311 Fax. +44 (020) 8643 8232 www.crownagents.com	UNITED KINGDOM Intertek Group plc 25 Savile Row London Greater London W1S 2ES United Kingdom Tel. +44 20 7396 3400

2. Sampling

Compliance activities are often based on a *sampling* of the product instead of 100 percent inspection. For this manual, sampling is defined as the process of selecting a small, representative quantity from a much larger batch or consignment of products.

Inspecting a representative sample from a large body of goods allows for judgment about the quality of the entire batch or consignment without looking at each individual unit. However, there is no guarantee that a randomly selected sample will represent the goods from which it comes; steps must be taken to improve its reliability. Statistical sampling plans, such as ISO 2859, help provide the necessary assurances. ISO 2859 is discussed later in this document; selected pages appear as section E of this appendix. Readers seeking additional explanation should refer to *Chapter One- Essential Elements of Condom Quality Assurance* in the WHO Model Condom Specification.

An independent sampling organization, or the laboratory contracted for testing, should do the sampling; not the factory producing the product, for obvious reasons. Samples, once taken, must be sealed and dispatched under the sampler's supervision.

ISO 2859–Statistical Sampling

Statistical evaluations are made according to the International Organization for Standardization Sampling Procedures and Tables for Inspection by Attributes (ISO 2859-1). Relevant ISO 2859 tables are in section E of this appendix. Please refer to them as you read the following explanation of their use:

Table I establishes a Sample Size Code Letter based on the lot size (total number of units to be represented by the test result) and the level of inspection (single, double; normal, tightened, reduced, etc.) considered appropriate for the situation and the specific attribute.[58] Inspection levels are indicated in the product specification in the bidding and contract documents.

The column in table I, *Lot or Batch Size*, shows the number of units that make up the lot. For example, in a lot formed by 10,000 units, a sample corresponding to the letter ***L*** would be drawn if a general inspection level (II) were to be applied.

Table I is also used to establish the number of multiple unit boxes from which to draw the sample products. For example, if the 10,000 units were packed in 100 multiple unit boxes, according to level II, the sample of ***L*** units should be taken from a number of multiple boxes that correspond to letter ***F***.

Tables II and III show the actual number of samples (sample size) to be drawn and the number of non-conformers allowed—AQL. A sample size corresponding to each code letter is shown in the adjacent *Sample Size* column.

To know what sample size corresponds to the code letters ***L*** and ***F*** in the example given above, table IIA (Single Sampling Plan, Normal Inspection) or table IIIA (Double Sampling Plan, Normal Inspection) should be consulted, depending on the type of sampling plan designated for the test. The corresponding values on table IIA are ***200*** for code letter ***L*** and ***20*** for code letter ***F***. This means that for a lot or batch of 100 multiple boxes, 20 would be chosen, out of which a proportionate number of units would be taken to gather the 200 that should make up the sample for inspection. The sample should be taken from the multiple boxes at random.

Inspection-Level Recommendations

If a new supplier or a manufacturer is just beginning operations, the first five lots should be inspected at a *tightened* level using table IIB (Single Plan, Tightened Inspection) or table IIIB (Double Plan, Tightened Inspection), as designated for the tests. If the first five lots are consecutively approved, change to a *normal* inspection (less strict) level (tables IIA or IIIA).

[58] The WHO model condom specification uses G-1 for performance requirements, S-2 for design requirements and S-3 for packaging requirements

A *normal* inspection can be changed to *reduced* (less strict) level (tables IIC or IIIC), if the following requirements are met:

- Satisfactory results from the original inspection of the last 10 lots received.
- The total number of defective units found in those 10 lots is the same, or smaller, than the number indicated on table VIII (Limit Numbers for Reduced Inspection). If multiple or double sampling plans are used, the results of the total number of samples will be considered, not just the ones that correspond to the first sampling.

Change *normal level inspection* (tables IIA or IIIA) to *tightened* (more strict) level (tables IIB or IIIB) when two out of five consecutive lots in the original inspection have been rejected.

When *tightened* inspection is in effect, *normal* inspection can be instituted after five consecutive lots or batches have been considered acceptable on original inspection. If 10 consecutive production lots remain on *tightened* inspection, then production should be stopped until problems have been resolved.

Re-submitted lots or batches. Lots or batches found unacceptable must be resubmitted for inspection only after all units are re-examined or retested, and all defective units are removed or defects corrected. The responsible authority must determine whether normal or tightened inspection will be used, and whether re-inspection will include all types or classes of defects or particular types or classes of defects that caused the initial rejection.

3. Testing

If laboratory testing is included in the pre-shipment compliance program, the inspection agent should be directed to randomly select a pre-determined number of samples from each manufacturing lot and forward them to a designated laboratory. Condom testing involves a relatively large sample size, while pharmaceutical product testing (including oral and injectable contraceptives) usually requires only a small sample. For any typical batch of products supplied by a reputable manufacturer, one set of samples is sufficient for analytical tests. If any possibility exists that samples are deteriorated or adulterated, at least one additional set of samples should be available for confirmation of test results. Cost depends on the product and the tests required.

To avoid charges and counter-charges of prejudice (e.g., disputed results), an independent accredited laboratory should do the testing, not the purchaser's or the supplier's personnel and laboratories.

Classification of Defects and Acceptable Quality Levels

Purchasers are responsible for setting limits on the maximum percentage of defects they will accept. Defects are classified as critical, major, or minor for assigning acceptance quality levels (AQLs).

Critical defect	A defect which, based on experience and professional criteria, makes the product dangerous or not viable for its intended use.
Major defect	A defect that is unlikely to reduce usability, but may make product use more difficult; however, it does not have the safety and efficacy risk associated with a critical defect.
Minor defect	A defect that is unlikely to affect usability of the product, but represents a departure from the specifications.

The quality of a batch of products is not just about the item—pills injectables, condoms, etc.—but, also about the packaging and packing that protect the product from deterioration and about markings necessary for safe storage and use. *Shipping cartons* contain *inner boxes;* which, in turn, contain individual *units* or *packages*. Therefore, three levels of packaging contribute to the overall quality of a product.

For important performance and safety properties, the AQL should be set very low; it should be set at zero for critical defects for pharmaceutical products and IUDs. For properties that are less important and do not affect the performance, slightly higher limits are often set: 1 percent for major defects; 4 percent for minor defects. For condoms, the WHO guideline specifies AQL levels for different properties, ranging from 0.25 and 0.4 at the critical level, through AQL 1, 1.5, and 2.5 at the major level; and 4.0 at the minor level.

Sample Compliance Program

Section B of this appendix contains a *Sample Compliance Program,* which has wording that is appropriate for use in bidding documents and specifications for oral or injectable contraceptives. It can be adapted for procuring IUDs, as well. For condoms, refer to the *WHO Guideline and Model Specification for Condom Procurement.*

Visual inspection review guidelines for OCs, injectable contraceptives, and IUDs are included at the end of this appendix.

B. Sample Compliance Program (OCs, injectables)

Prior to shipment, the purchaser, or his appointed representative, has the right to sample and inspect each consignment of oral contraceptives and injectable contraceptives at the factory or supplier's warehouse, in accordance with ISO 2859 Inspection by Attributes and Technical Specification _____ of this contract.

1. Packaging, Packing, and Marking

One hundred percent of the exterior shipping cartons will be examined for—

i. general physical characteristics and condition

ii. markings per technical specification _____

A representative sample of the inner boxes will be drawn from the exterior shipping cartons at General Inspection Level II, or at the discretion of the purchaser, General Inspection Level III, and Single Sampling Plan for Normal Inspection.

The sample will be examined for—

i. general physical characteristics per technical specification _____

ii. markings per technical specification _____

All parts of the samples, including the exterior shipping cartons, inner boxes, and primary packaging will be further inspected and any defects classified as follows:

Critical

- The shipping documents do not match the information on the primary package.
- Primary package[59] or its contents is damaged.

[59] Blister pack, ampoule

- Primary package has illegible or missing text or markings.
- Batch/lot number or expiration date is incorrect or missing from the labeling.
- Product information sheet does not match the product.
- Package insert or information sheet is missing.
- Shipping carton is poorly closed or broken.
- Inner boxes are in bad condition, open, dirty, or torn/broken.
- Individual boxes are missing from the multiple-unit shipping cartons.
- Batch/lot number or expiration date is incorrect or missing from the inner boxes.
- Foreign matter is in the inner boxes.

Major

- Manufacturer's national registration number is missing on the inner boxes.
- Goods are missing from the inner boxes.
- Manufacturer's name, address, or importing country's registration number is missing from the inner boxes.
- Package insert or information sheet is illegible, dirty, or torn.
- Labeling is missing from the inner boxes.
- Instructions for storage are missing from the inner boxes.

Minor

- Printing on primary package is defective, but legible.

For critical defects, the AQL must be zero (0) percent; for major defects, the AQL must be 1 percent; and for minor defects, the AQL must be 4 percent.

2. Tablet/Ampoule

At the discretion of the purchaser, all or part of the sample can be sent to a qualified independent laboratory to confirm any or all of the manufacturer's test data on the final product. (for OC's only: In addition, a package seal integrity test must be performed.)

A certificate of analysis for production lot(s) represented by test samples must be made available to the inspector and/or purchaser, upon request. The certificate shall list all the tests performed, their specifications, and the actual test results. In each case, test results must meet pharmacopoeia limits.

3. Resolution of Defects

a. Packaging, Packing, and Markings

- The supplier must correct defects in the exterior shipping carton markings before shipment.
- All critical defects must be corrected and re-inspected at the supplier's expense, or all products from the same production lot will be rejected.
- The supplier must correct major defects to the satisfaction of the purchaser, prior to shipment.
- Minor defects will be resolved, on a case-by-case basis, to the satisfaction of the purchaser.

b. Product

- Any deviation from the manufacturer's certificate of analysis, product specification, or pharmacopoeia limits will result in the rejection of the entire production lot.

C. Sample Inspection Order (copy of Exhibit 51)

To: _____(*insert name of inspection agent/company*)

Date:

Contract Number:

Vendor: XYZ Corporation

Consignee: MOH, Government of Pakistan

INSPECTION ORDER

Inspect packing and marking for compliance with section _____ of attached technical specifications.

Inspection shall be conducted in accordance with ISO 2859-1, Inspection by Attributes.

Inspection level shall be S-3 with an AQL of 2.5%:

For exterior shipping cartons, the lot size shall be the number of exterior shipping cartons and the sample unit shall be one exterior shipping carton.

For other levels of packing, the lot size shall be the number of inner boxes and the sample unit shall be one inner box.

1. Inspect and score for defects as follows

Defects*	
Contents	Quantity of goods not as specified, packets or strips not as specified
Marking	Omitted, incorrect, illegible; of an improper size, location, sequence, or method of application
Materials	Packaging/packing materials not as specified, missing, damaged, or not serviceable
Workmanship	Shipping cartons inadequately closed and secured; poor application of internal packaging and packing material; distorted inner boxes

** Examination of closure defects shall be performed on units that are fully prepared for delivery.*

a. Exterior shipping cartons selected at random from lot proposed for delivery.
b. Inner boxes selected at random from sample shipping cartons.

2. Examine Documentation

a. Refer to attached shipping instructions and confirm that all documents listed are complete.
b. Confirm that the values on the certificates of analysis for the lot(s) prepared for shipment are within the range listed in the product's National Regulatory Authority (NRA) dossier and/or specified in the relevant pharmacopoeia, per the procurement specification.

3. Provide a written report for approval by the Government of Pakistan on packing and marking, and documentation; prior to release of a clean bill of goods.

4. Unless otherwise specified in writing, the inspection agent is not authorized to sign the *Authorization for Shipment* form.

D. Visual Inspection Review Guidelines

Visual Inspection Review Guidelines

Oral Contraceptives

Oral contraceptives are available in cycles of 21 or 28 tablets. In the 28-day cycle, seven placebo or iron tablets are provided, in addition to the contraceptive tablets. Iron tablets are usually larger and brown in color. Most oral contraceptives are packed in blister packages with a cardboard over-pack. Frequently, three cycles are packed together in a sealed foil over-pack. Oral contraceptives shelf life ranges from three to five years at 37°C, although the most brands have a five-year shelf life. Blister packing provides good protection from adverse environmental conditions.

The labeling criteria listed below are comprehensive and useful for successfully identifying and managing the product, within the logistics system. However, not all contraceptives have these extensive labeling specifications. If any of the labeling criteria listed below are not applicable, mark the appropriate box in the N/A column. Product procurement specifications should be consulted prior to finalizing the inspection criteria.

Date: _____	Receipt report number: _____			
Product: _____	Lot number: _____			
Brand name: _____	Manufacturer: _____			
Expiration dale: _____	Date of manufacture: _____			
Inspection lot size: _____	Sample size: _____			
Warehouse location: _____	Second sample size: _____			
VISUAL INSPECTION CRITERIA	**MEETS CRITERIA**			**DEFECT CLASSIFICATION**
SHIPPING CARTONS Examine 100 percent of the shipping cartons against the shipping documents. Inspection criteria				
Carton labeling:	Yes	No	N/A	
Product/brand name	☐	☐	☐	Major
Lot/batch number	☐	☐	☐	Major
Expiration date	☐	☐	☐	Major
Manufacturer's name. address	☐	☐	☐	Minor
Date of manufacture	☐	☐	☐	Minor
Contents and quantity	☐	☐	☐	Minor
Drug registration number	☐	☐	☐	Minor
Storage instructions	☐	☐	☐	Minor
Carton condition/content:				
Carton in good condition. undamaged	☐	☐	☐	Major
All inner boxes present, none missing	☐	☐	☐	Major
Proper nap/closure	☐	☐	☐	Minor

Oral Contraceptives (*continued*)

VISUAL INSPECTION CRITERIA	MEETS CRITERIA			DEFECT CLASSIFICATION
INNER BOXES Inspection criteria				
Inner box labeling:	Yes	No	N/A	
Product/brand name	☐	☐	☐	Critical
Lot/batch number	☐	☐	☐	Critical
Expiration date	☐	☐	☐	Critical
Date of manufacture	☐	☐	☐	Minor
Manufacturer's name and address	☐	☐	☐	Minor
Contents and quantity	☐	☐	☐	Minor
Drug registration number	☐	☐	☐	Minor
Storage instructions	☐	☐	☐	Minor
Inner box condition/content:				
Inner box in good condition. undamaged	☐	☐	☐	Major
All unit packages present, none missing	☐	☐	☐	Major
Inner box contains no foreign matter	☐	☐	☐	Minor
UNIT PACKAGES: Inspection criteria				
Unit package labeling:				
Product/brand name	☐	☐	☐	Critical
Lot/batch number	☐	☐	☐	Critical
Expiration date	☐	☐	☐	Critical
Date of manufacture	☐	☐	☐	Critical
Manufacturer's name and address	☐	☐	☐	Critical
Product use instructions	☐	☐	☐	Critical
Arrow indicating sequence of pills	☐	☐	☐	Critical
Contents and quantity	☐	☐	☐	Major
Drug registration number	☐	☐	☐	Major
Storage instructions	☐	☐	☐	Minor
Print on unit package is legible	☐	☐	☐	Minor
Product use instructions properly folded	☐	☐	☐	Minor
Unit package condition/content:				
Unit package in good condition (undamaged, unopened)	☐	☐	☐	Critical
Pills in good condition (unbroken, correct color, none missing)	☐	☐	☐	Critical
Good package seal, no breaks	☐	☐	☐	Critical
Unit package contains no foreign matter	☐	☐	☐	Critical

Visual Inspection Review Guidelines

Injectable Contraceptives

Injectable contraceptive are available in several formulations, including oil-based and aqueous suspension and dosage forms. Contraceptive protection, per dose, ranges from one month to three months, depending on the product. Injectables are available in pre-filled syringes; but most are available in single- or multi-dose vials or ampoules, with disposable syringes. Shelf life for injectable contraceptives ranges from two to five years depending on the formulation. Recommended storage temperature is usually 15–30°C. Storage temperature is critical to product stability; oil-based solutions become rancid at elevated temperatures. Manufacturers' recommended storage conditions should be followed,

The labeling criteria listed below are comprehensive and useful in successfully identifying and managing the product within the logistics system. Not all contraceptives have these extensive labeling specifications. If any of the labeling criteria listed below are not applicable, mark the appropriate box in the N/A column. Product procurement specifications should be consulted prior to finalizing the inspection criteria.

Date: _____	Receipt report number: _____			
Product: _____	Lot number: _____			
Brand name: _____	Manufacturer: _____			
Expiration dale: _____	Date of manufacture: _____			
Inspection lot size: _____	Sample size: _____			
Warehouse location: _____	Second sample size: _____			
VISUAL INSPECTION CRITERIA	**MEETS CRITERIA**			**DEFECT CLASSIFICATION**
SHIPPING CARTONS Examine 100 percent of the shipping cartons against the shipping documents. Inspection criteria				
Carton labeling:	Yes	No	N/A	
Product/brand name	☐	☐	☐	Major
Lot/batch number	☐	☐	☐	Major
Expiration date	☐	☐	☐	Major
Manufacturer's name and address	☐	☐	☐	Minor
Date of manufacture	☐	☐	☐	Minor
Contents and quantity	☐	☐	☐	Minor
Drug registration number	☐	☐	☐	Minor
Storage instructions	☐	☐	☐	Minor
Carton condition/content:				
Carton in good condition. undamaged	☐	☐	☐	Major
All inner boxes present, none missing	☐	☐	☐	Major
Proper nap/closure	☐	☐	☐	Minor

Injectable Contraceptives (*continued*)

VISUAL INSPECTION CRITERIA	MEETS CRITERIA			DEFECT CLASSIFICATION
INNER BOXES Inspection criteria				
Inner box labeling:	Yes	No	N/A	
Product/brand name	☐	☐	☐	Critical
Lot/batch number	☐	☐	☐	Critical
Expiration date	☐	☐	☐	Critical
Date of manufacture	☐	☐	☐	Minor
Manufacturer's name and address	☐	☐	☐	Minor
Contents and quantity	☐	☐	☐	Minor
Drug registration number	☐	☐	☐	Minor
Storage instructions	☐	☐	☐	Minor
Inner box condition/content:				
Inner box in good condition. undamaged	☐	☐	☐	Major
All unit packages present, none missing	☐	☐	☐	Major
Inner box contains no foreign matter	☐	☐	☐	Minor
UNIT PACKAGES: Inspection criteria				
Unit package labeling:				
Product/brand name	☐	☐	☐	Critical
Lot/batch number	☐	☐	☐	Critical
Expiration date	☐	☐	☐	Critical
Date of manufacture	☐	☐	☐	Critical
Manufacturer's name and address	☐	☐	☐	Critical
Product use instructions	☐	☐	☐	Critical
Dosage	☐	☐	☐	Critical
Contents and quantity of doses	☐	☐	☐	Major
Drug registration number	☐	☐	☐	Major
Storage instructions	☐	☐	☐	Minor
Unit package condition/content:				
Glass vial or ampoule in good condition (undamaged, unopened)	☐	☐	☐	Critical
Vial or ampoule free of foreign matter	☐	☐	☐	Critical
Vial or ampoule free of leakage	☐	☐	☐	Critical
Vial or ampoule free of solid material or caking	☐	☐	☐	Critical
Correct color	☐	☐	☐	Critical
Good vial seal no breaks	☐	☐	☐	Critical

Visual Inspection Review Guidelines

Intrauterine Devices

IUDs come in a variety of designs. Most IUDs in use today have a frame of molded plastic with some form of copper attached. The shelf life for IUDs currently ranges from three to seven years.

The labeling criteria listed below are comprehensive and useful in successfully identifying and managing the product within the logistics system. Not all contraceptives have these extensive labeling specifications. If any of the labeling criteria listed below are not applicable, mark the appropriate box in the N/A column. Product procurement specifications should be consulted prior to finalizing the inspection criteria.

Date: _____	Receipt report number: _____			
Product: _____	Lot number: _____			
Brand name: _____	Manufacturer: _____			
Expiration dale: _____	Date of manufacture: _____			
Inspection lot size: _____	Sample size: _____			
Warehouse location: _____	Second sample size: _____			
VISUAL INSPECTION CRITERIA	**MEETS CRITERIA**			**DEFECT CLASSIFICATION**
SHIPPING CARTONS Examine 100 percent of the shipping cartons against the shipping documents. Inspection criteria				
Carton labeling:	Yes	No	N/A	
Product/brand name	☐	☐	☐	Major
Lot/batch number	☐	☐	☐	Major
Expiration date	☐	☐	☐	Major
Manufacturer's name and address	☐	☐	☐	Minor
Date of manufacture	☐	☐	☐	Minor
Contents and quantity	☐	☐	☐	Minor
Drug or device registration number	☐	☐	☐	Minor
Storage instructions	☐	☐	☐	Minor
Carton condition/content:				
Carton in good condition. undamaged	☐	☐	☐	Major
All inner boxes present, none missing	☐	☐	☐	Major
Proper nap/closure	☐	☐	☐	Minor

Intrauterine Devices (*continued*)

VISUAL INSPECTION CRITERIA	MEETS CRITERIA			DEFECT CLASSIFICATION
INNER BOXES Inspection criteria				
Inner box labeling:	Yes	No	N/A	
Product/brand name	☐	☐	☐	Critical
Lot/batch number	☐	☐	☐	Critical
Expiration date	☐	☐	☐	Critical
Manufacturer's name. address	☐	☐	☐	Minor
Date of manufacture	☐	☐	☐	Minor
Contents and quantity	☐	☐	☐	Minor
Drug or device registration number	☐	☐	☐	Minor
Storage instructions	☐	☐	☐	Minor
Inner box condition/content:				
Inner box in good condition. undamaged	☐	☐	☐	Major
All unit packages present, none missing	☐	☐	☐	Major
Inner box contains no foreign matter	☐	☐	☐	Minor
UNIT PACKAGES: Inspection criteria				
Unit package labeling:				
Product/brand name	☐	☐	☐	Critical
Lot/batch number	☐	☐	☐	Critical
Expiration date	☐	☐	☐	Critical
Date of manufacture	☐	☐	☐	Critical
Manufacturer's name and address	☐	☐	☐	Critical
Product use instructions	☐	☐	☐	Critical
Product information card within sterile package	☐	☐	☐	Critical
Contents and quantity	☐	☐	☐	Major
Drug or device registration number	☐	☐	☐	Major
Print on insert card or use instructions is legible	☐	☐	☐	Minor
Unit package condition/content:				
Unit package in good condition (undamaged, unopened)	☐	☐	☐	Critical
All components present. none missing (inserter tube; flange; IUD; tail; copper components, if relevant; inserter rod; insert card; or information)	☐	☐	☐	Critical
Components in good condition. not misshapen	☐	☐	☐	Critical
Good package seal no breaks	☐	☐	☐	Critical
Unit package contains no foreign matter	☐	☐	☐	Critical

Visual Inspection Review Guidelines

Sub-dermal Implants

Two types of sub-dermal Implants are primarily available. The two rod implant is supplied as a set—one sealed, sterile plastic pouch containing two rods, each filled with 75mg of levonorgestrel; for use in one woman. The single rod implant has 68mg of etonogestrel, preloaded in the needle of a disposable applicator. The sterile applicator containing the implant is in a blister pack. The shelf life for implants currently ranges from three to five years.

The labeling criteria listed below are comprehensive and useful in successfully identifying and managing the product within the logistics system. Not all contraceptives have these extensive labeling specifications. If any of the labeling criteria listed below are not applicable, mark the appropriate box in the N/A column. Product procurement specifications should be consulted prior to finalizing the inspection criteria.

Date: _____	Receipt report number: _____			
Product: _____	Lot number: _____			
Brand name: _____	Manufacturer: _____			
Expiration dale: _____	Date of manufacture: _____			
Inspection lot size: _____	Sample size: _____			
Warehouse location: _____	Second sample size: _____			
VISUAL INSPECTION CRITERIA	**MEETS CRITERIA**			**DEFECT CLASSIFICATION**
SHIPPING CARTONS Examine 100 percent of the shipping cartons against the shipping documents. Inspection criteria				
Carton labeling:	Yes	No	N/A	
Product/brand name	☐	☐	☐	Major
Lot/batch number	☐	☐	☐	Major
Expiration date	☐	☐	☐	Major
Manufacturer's name and address	☐	☐	☐	Minor
Date of manufacture	☐	☐	☐	Minor
Contents and quantity	☐	☐	☐	Minor
Drug or device registration number	☐	☐	☐	Minor
Storage instructions	☐	☐	☐	Minor
Carton condition/content:				
Carton in good condition. undamaged	☐	☐	☐	Major
All inner boxes present, none missing	☐	☐	☐	Major
Proper nap/closure	☐	☐	☐	Minor

Sub-dermal Implants (*continued*)

VISUAL INSPECTION CRITERIA	MEETS CRITERIA			DEFECT CLASSIFICATION
INNER BOXES Inspection criteria				
Inner box labeling:	Yes	No	N/A	
Product/brand name	☐	☐	☐	Critical
Lot/batch number	☐	☐	☐	Critical
Expiration date	☐	☐	☐	Critical
Manufacturer's name. address	☐	☐	☐	Minor
Date of manufacture	☐	☐	☐	Minor
Contents and quantity	☐	☐	☐	Minor
Drug or device registration number	☐	☐	☐	Minor
Storage instructions	☐	☐	☐	Minor
Inner box condition/content:				
Inner box in good condition. undamaged	☐	☐	☐	Major
All unit packages present, none missing	☐	☐	☐	Major
Inner box contains no foreign matter	☐	☐	☐	Minor
UNIT PACKAGES: Inspection criteria				
Unit package labeling:				
Product/brand name	☐	☐	☐	Critical
Lot/batch number	☐	☐	☐	Critical
Expiration date	☐	☐	☐	Critical
Date of manufacture	☐	☐	☐	Critical
Manufacturer's name and address	☐	☐	☐	Critical
Product use instructions	☐	☐	☐	Critical
Product information card within sterile package	☐	☐	☐	Critical
Contents and quantity	☐	☐	☐	Major
Drug or device registration number	☐	☐	☐	Major
Print on insert card or use instructions is legible	☐	☐	☐	Minor
Unit package condition/content:				
Unit package in good condition (undamaged, unopened)	☐	☐	☐	Critical
All components present. none missing (Separate Trocar in case of two rod implants)	☐	☐	☐	Critical
Components in good condition. not misshapen	☐	☐	☐	Critical
Good package seal, no breaks	☐	☐	☐	Critical
Unit package contains no foreign matter	☐	☐	☐	Critical

Visual Inspection Review Guidelines

Emergency Contraceptive Pills

Emergency contraceptive (EC) pills come in one pack of two 0.75mg levonorgestrel tablets or a single tablet of 1.50mg. The EC pills are packed in blister packages with a cardboard over-pack. Shelf life ranges from three to five years at 37°C, although most brands have a five-year shelf life. Blister packing provides good protection from adverse environmental conditions.

The labeling criteria listed below are comprehensive and useful in successfully identifying and managing the product within the logistics system. Not all contraceptives have these extensive labeling specifications. If any of the labeling criteria listed below are not applicable, mark the appropriate box in the N/A column. Product procurement specifications should be consulted prior to finalizing the inspection criteria.

Date: _____	Receipt report number: _____			
Product: _____	Lot number: _____			
Brand name: _____	Manufacturer: _____			
Expiration dale: _____	Date of manufacture: _____			
Inspection lot size: _____	Sample size: _____			
Warehouse location: _____	Second sample size: _____			
VISUAL INSPECTION CRITERIA	**MEETS CRITERIA**			**DEFECT CLASSIFICATION**
SHIPPING CARTONS Examine 100 percent of the shipping cartons against the shipping documents. Inspection criteria				
Carton labeling:	Yes	No	N/A	
Product/brand name	☐	☐	☐	Major
Lot/batch number	☐	☐	☐	Major
Expiration date	☐	☐	☐	Major
Manufacturer's name. address	☐	☐	☐	Minor
Date of manufacture	☐	☐	☐	Minor
Contents and quantity	☐	☐	☐	Minor
Drug registration number	☐	☐	☐	Minor
Storage instructions	☐	☐	☐	Minor
Carton condition/content:				
Carton in good condition. undamaged	☐	☐	☐	Major
All inner boxes present, none missing	☐	☐	☐	Major
Proper nap/closure	☐	☐	☐	Minor

Emergency Contraceptive Pills (*continued*)

VISUAL INSPECTION CRITERIA	MEETS CRITERIA			DEFECT CLASSIFICATION
INNER BOXES Inspection criteria				
Inner box labeling:	Yes	No	N/A	
Product/brand name	☐	☐	☐	Critical
Lot/batch number	☐	☐	☐	Critical
Expiration date	☐	☐	☐	Critical
Date of manufacture	☐	☐	☐	Minor
Manufacturer's name and address	☐	☐	☐	Minor
Contents and quantity	☐	☐	☐	Minor
Drug registration number	☐	☐	☐	Minor
Storage instructions	☐	☐	☐	Minor
Inner box condition/content:				
Inner box in good condition, undamaged	☐	☐	☐	Major
All unit packages present, none missing	☐	☐	☐	Major
Inner box contains no foreign matter	☐	☐	☐	Minor
UNIT PACKAGES: Inspection criteria				
Unit package labeling:				
Product/brand name	☐	☐	☐	Critical
Lot/batch number	☐	☐	☐	Critical
Expiration date	☐	☐	☐	Critical
Date of manufacture	☐	☐	☐	Critical
Manufacturer's name and address	☐	☐	☐	Critical
Product use instructions	☐	☐	☐	Critical
Arrow indicating sequence of pills	☐	☐	☐	Critical
Contents and quantity	☐	☐	☐	Major
Drug registration number	☐	☐	☐	Major
Storage instructions	☐	☐	☐	Minor
Print on unit package is legible	☐	☐	☐	Minor
Product use instructions properly folded	☐	☐	☐	Minor
Unit package condition/content:				
Unit package in good condition (undamaged, unopened)	☐	☐	☐	Critical
Pills in good condition (unbroken, correct color, none missing)	☐	☐	☐	Critical
Good package seal, no breaks	☐	☐	☐	Critical
Unit package contains no foreign matter	☐	☐	☐	Critical

Table 1 – Sample size code letters (see 10.1 and 10.2)

E. ISO 2859-1 Relevant Tables

Lot Size		Special Inspection Levels				General Inspection Levels		
		S-1	S-2	S-3	S-4	I	II	III
2 to	8	A	A	A	A	A	A	B
9 to	15	A	A	A	A	A	B	C
16 to	25	A	A	B	B	B	C	D
26 to	50	A	B	B	C	C	D	E
51 to	90	B	B	C	C	C	E	F
91 to	150	B	B	C	D	D	F	G
151 to	280	B	C	D	E	E	G	H
281 to	500	B	C	D	E	F	H	J
501 to	1,200	C	C	E	F	G	J	K
1,201 to	3,200	C	D	E	G	H	K	L
3,201 to	10,000	C	D	F	G	J	L	M
10,001 to	35,000	C	D	F	H	K	M	N
35,001 to	150,000	D	E	G	J	L	N	P
150,001 to	500,000	D	E	G	J	M	P	Q
500,001 and over		D	E	H	K	N	Q	R

Table 2-A — Single sampling plans for normal inspection (Master table)

Sample size code letter	Sample size	Acceptance quality limit, AQL, in percent nonconforming items and nonconformities per 100 items (normal inspection)																										
		0,010	0,015	0,025	0,040	0,065	0,10	0,15	0,25	0,40	0,65	1,0	1,5	2,5	4,0	6,5	10	15	25	40	65	100	150	250	400	650	1 000
		Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re
A	2	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	0 1	⇩	⇩	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22	30 31	
B	3	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	0 1	⇧	⇩	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22	30 31	44 45	
C	5	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	0 1	⇧	⇧	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22	30 31	44 45		
D	8	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	0 1	⇧	⇧	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22	30 31	44 45			
E	13	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	0 1	⇧	⇧	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22	30 31	44 45				
F	20	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	0 1	⇧	⇧	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22							
G	32	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	0 1	⇧	⇧	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22								
H	50	⇩	⇩	⇩	⇩	⇩	⇩	⇩	0 1	⇧	⇧	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22									
J	80	⇩	⇩	⇩	⇩	⇩	⇩	0 1	⇧	⇧	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22										
K	125	⇩	⇩	⇩	⇩	⇩	0 1	⇧	⇧	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22											
L	200	⇩	⇩	⇩	⇩	0 1	⇧	⇧	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22												
M	315	⇩	⇩	⇩	0 1	⇧	⇧	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22													
N	500	⇩	⇩	0 1	⇧	⇧	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22	⇧													
P	800	⇩	0 1	⇧	⇩	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22	⇧														
Q	1 250	0 1	⇧	⇩	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22	⇧															
R	2 000	⇧		1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22	⇧																

⇩ = Use the first sampling plan below the arrow. If sample size equals, or exceeds, lot size, carry out 100 % inspection.

⇧ = Use the first sampling plan above the arrow.

Ac = Acceptance number

Re = Rejection number

Table 2-B — Single sampling plans for tightened inspection (Master table)

Sample size code letter	Sample size	Acceptance quality limit, AQL, in percent nonconforming items and nonconformities per 100 items (tightened inspection)																										
		0,010	0,015	0,025	0,040	0,065	0,10	0,15	0,25	0,40	0,65	1,0	1,5	2,5	4,0	6,5	10	15	25	40	65	100	150	250	400	650	1 000
		Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re
A	2	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	0 1	⇩	⇩	1 2	2 3	3 4	5 6	8 9	12 13	18 19	27 28
B	3	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	0 1	⇩	⇩	1 2	2 3	3 4	5 6	8 9	12 13	18 19	27 28	41 42	⇧
C	5	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	0 1	⇩	⇩	1 2	2 3	3 4	5 6	8 9	12 13	18 19	27 28	41 42	⇧	⇧
D	8	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	0 1	⇩	⇩	1 2	2 3	3 4	5 6	8 9	12 13	18 19	27 28	41 42	⇧	⇧	⇧
E	13	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	0 1	⇩	⇩	⇩	1 2	2 3	3 4	5 6	8 9	12 13	18 19	27 28	41 42	⇧	⇧	⇧	⇧
F	20	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	0 1	⇩	⇩	⇩	⇩	1 2	2 3	3 4	5 6	8 9	12 13	18 19	⇧	⇧	⇧	⇧	⇧	⇧
G	32	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	0 1	⇩	⇩	1 2	2 3	3 4	5 6	8 9	12 13	18 19	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧
H	50	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	0 1	⇩	⇩	1 2	2 3	3 4	5 6	8 9	12 13	18 19	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧
J	80	⇩	⇩	⇩	⇩	⇩	⇩	⇩	0 1	⇩	⇩	1 2	2 3	3 4	5 6	8 9	12 13	18 19	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧
K	125	⇩	⇩	⇩	⇩	⇩	⇩	0 1	⇩	⇩	1 2	2 3	3 4	5 6	8 9	12 13	18 19	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧
L	200	⇩	⇩	⇩	⇩	⇩	0 1	⇩	⇩	1 2	2 3	3 4	5 6	8 9	12 13	18 19	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧
M	315	⇩	⇩	⇩	⇩	0 1	⇩	⇩	1 2	2 3	3 4	5 6	8 9	12 13	18 19	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧
N	500	⇩	⇩	⇩	0 1	⇩	⇩	1 2	2 3	3 4	5 6	8 9	12 13	18 19	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧
P	800	⇩	⇩	0 1	⇩	⇩	1 2	2 3	3 4	5 6	8 9	12 13	18 19	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧
Q	1 250	⇩	0 1	⇩	⇩	1 2	2 3	3 4	5 6	8 9	12 13	18 19	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧
R	2 000	0 1	⇧	⇩	1 2	2 3	3 4	5 6	8 9	12 13	18 19	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧
S	3 150			1 2																								

⇩ = Use the first sampling plan below the arrow. If sample size equals, or exceeds, lot size, carry out 100 % inspection.

⇧ = Use the first sampling plan above the arrow.

Ac = Acceptance number

Re = Rejection number

Table 2-C — Single sampling plans for reduced inspection (Master table)

Sample size code letter	Sample size	Acceptance quality limit, AQL, in percent nonconforming items and nonconformities per 100 items (reduced inspection)																									
		0,010	0,015	0,025	0,040	0,065	0,10	0,15	0,25	0,40	0,65	1,0	1,5	2,5	4,0	6,5	10	15	25	40	65	100	150	250	400	650	1 000
		Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re
A	2	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	0 1	↓	↓	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22	30 31
B	2	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	0 1	↑	↓	↓	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22	30 31
C	2	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	0 1	↑	↓	↓	1 2	2 3	3 4	5 6	6 7	8 9	10 11	14 15	21 22	↑
D	3	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	0 1	↑	↓	↓	1 2	2 3	3 4	5 6	6 7	8 9	10 11	14 15	21 22	↑	↑
E	5	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	0 1	↑	↓	↓	1 2	2 3	3 4	5 6	6 7	8 9	10 11	14 15	21 22	↑	↑	↑
F	8	↓	↓	↓	↓	↓	↓	↓	↓	↓	0 1	↑	↓	↓	1 2	2 3	3 4	5 6	6 7	8 9	10 11	↑	↑	↑	↑	↑	↑
G	13	↓	↓	↓	↓	↓	↓	↓	↓	0 1	↑	↓	↓	1 2	2 3	3 4	5 6	6 7	8 9	10 11	↑	↑	↑	↑	↑	↑	↑
H	20	↓	↓	↓	↓	↓	↓	↓	0 1	↑	↓	↓	1 2	2 3	3 4	5 6	6 7	8 9	10 11	↑	↑	↑	↑	↑	↑	↑	↑
J	32	↓	↓	↓	↓	↓	↓	0 1	↑	↓	↓	1 2	2 3	3 4	5 6	6 7	8 9	10 11	↑	↑	↑	↑	↑	↑	↑	↑	↑
K	50	↓	↓	↓	↓	↓	0 1	↑	↓	↓	1 2	2 3	3 4	5 6	6 7	8 9	10 11	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑
L	80	↓	↓	↓	↓	0 1	↑	↓	↓	1 2	2 3	3 4	5 6	6 7	8 9	10 11	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑
M	125	↓	↓	↓	0 1	↑	↓	↓	1 2	2 3	3 4	5 6	6 7	8 9	10 11	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑
N	200	↓	↓	0 1	↑	↓	↓	1 2	2 3	3 4	5 6	6 7	8 9	10 11	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑
P	315	↓	0 1	↑	↓	↓	1 2	2 3	3 4	5 6	6 7	8 9	10 11	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑
Q	500	0 1	↑	↑	↓	1 2	2 3	3 4	5 6	6 7	8 9	10 11	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑
R	800	↑	↑	↑	1 2	2 3	3 4	5 6	6 7	8 9	10 11	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑

↓ = Use the first sampling plan below the arrow. If sample size equals, or exceeds, lot size, carry out 100 % inspection.

↑ = Use the first sampling plan above the arrow.

Ac = Acceptance number

Re = Rejection number

Table 3-A — Double sampling plans for normal inspection (Master table)

Sample size code letter	Sample	Sample size	Cumulative sample size	Acceptance quality limit, AQL, in percent nonconforming items and nonconformities per 100 items (normal inspection)																												
				0,010	0,015	0,025	0,040	0,065	0,10	0,15	0,25	0,40	0,65	1,0	1,5	2,5	4,0	6,5	10	15	25	40	65	100	150	250	400	650	1 000
				Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re
A				⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	*	⇩	*	*	*	*	*	*	*	*	*	*	*	*	*
B	First	2	2														*	⇧	⇩	0 2	0 3	1 3	2 5	3 6	5 9	7 11	11 16	17 22	25 31		
	Second	2	4																	1 2	3 4	4 5	6 7	9 10	12 13	18 19	26 27	37 38	56 57		
C	First	3	3												⇩		⇧	⇩	0 2	0 3	1 3	2 5	3 6	5 9	7 11	11 16	17 22	25 31			
	Second	3	6													*			1 2	3 4	4 5	6 7	9 10	12 13	18 19	26 27	37 38	56 57			
D	First	5	5											⇩		*	⇧	⇩	0 2	0 3	1 3	2 5	3 6	5 9	7 11	11 16	17 22	25 31			
	Second	5	10																1 2	3 4	4 5	6 7	9 10	12 13	18 19	26 27	37 38	56 57			
E	First	8	8										⇩	*	⇧	⇩	0 2	0 3	1 3	2 5	3 6	5 9	7 11	11 16	17 22	25 31					
	Second	8	16														1 2	3 4	4 5	6 7	9 10	12 13	18 19	26 27	37 38	56 57					
F	First	13	13									⇩	*	⇧	⇩	0 2	0 3	1 3	2 5	3 6	5 9	7 11	11 16	⇧	⇧	⇧					
	Second	13	26													1 2	3 4	4 5	6 7	9 10	12 13	18 19	26 27								
G	First	20	20								⇩	*	⇧	⇩	0 2	0 3	1 3	2 5	3 6	5 9	7 11	11 16	⇧								
	Second	20	40												1 2	3 4	4 5	6 7	9 10	12 13	18 19	26 27									
H	First	32	32							⇩	*	⇧	⇩	0 2	0 3	1 3	2 5	3 6	5 9	7 11	11 16	⇧									
	Second	32	64											1 2	3 4	4 5	6 7	9 10	12 13	18 19	26 27										
J	First	50	50						⇩	*	⇧	⇩	0 2	0 3	1 3	2 5	3 6	5 9	7 11	11 16	⇧										
	Second	50	100										1 2	3 4	4 5	6 7	9 10	12 13	18 19	26 27											
K	First	80	80					⇩	*	⇧	⇩	0 2	0 3	1 3	2 5	3 6	5 9	7 11	11 16	⇧											
	Second	80	160									1 2	3 4	4 5	6 7	9 10	12 13	18 19	26 27												
L	First	125	125				⇩	*	⇧	⇩	0 2	0 3	1 3	2 5	3 6	5 9	7 11	11 16	⇧												
	Second	125	250								1 2	3 4	4 5	6 7	9 10	12 13	18 19	26 27													
M	First	200	200			⇩	*	⇧	⇩	0 2	0 3	1 3	2 5	3 6	5 9	7 11	11 16	⇧													
	Second	200	400							1 2	3 4	4 5	6 7	9 10	12 13	18 19	26 27														
N	First	315	315		⇩	*	⇧	⇩	0 2	0 3	1 3	2 5	3 6	5 9	7 11	11 16	⇧														
	Second	315	630						1 2	3 4	4 5	6 7	9 10	12 13	18 19	26 27															
P	First	500	500	⇩	*	⇧	⇩	0 2	0 3	1 3	2 5	3 6	5 9	7 11	11 16	⇧															
	Second	500	1 000					1 2	3 4	4 5	6 7	9 10	12 13	18 19	26 27																
Q	First	800	800	*	⇧	⇩	0 2	0 3	1 3	2 5	3 6	5 9	7 11	11 16	⇧																
	Second	800	1 600				1 2	3 4	4 5	6 7	9 10	12 13	18 19	26 27																	
R	First	1 250	1 250	⇧		0 2	0 3	1 3	2 5	3 6	5 9	7 11	11 16	⇧																	
	Second	1 250	2 500			1 2	3 4	4 5	6 7	9 10	12 13	18 19	26 27																		

⇩ = Use the first sampling plan below the arrow. If sample size equals, or exceeds, lot size, carry out 100 % inspection.

⇧ = Use the first sampling plan above the arrow.

Ac = Acceptance number

Re = Rejection number

* = Use the corresponding single sampling plan (or alternatively use the double sampling plan below, where available).

Table 3-B — Double sampling plans for tightened inspection (Master table)

Sample size code letter	Sample	Sample size	Cumulative sample size	Acceptance quality limit, AQL, in percent nonconforming items and nonconformities per 100 items (tightened inspection)																											
				0,010	0,015	0,025	0,040	0,065	0,10	0,15	0,25	0,40	0,65	1,0	1,5	2,5	4,0	6,5	10	15	25	40	65	100	150	250	400	650	1 000
				Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re
A				⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	*	*	*	*	*	*	*	*
B	First	2	2															⇩		⇩	0 2	0 3	1 3	2 5	4 7	6 10	9 14	15 20	23 29
	Second	2	4															*			1 2	3 4	4 5	6 7	10 11	15 16	23 24	34 35	52 53
C	First	3	3																⇩	0 2	0 3	1 3	2 5	4 7	6 10	9 14	15 20	23 29	
	Second	3	6														*	⇩		1 2	3 4	4 5	6 7	10 11	15 16	23 24	34 35	52 53	⇩
D	First	5	5													*	⇩		0 2	0 3	1 3	2 5	4 7	6 10	9 14	15 20	23 29		
	Second	5	10															⇩	1 2	3 4	4 5	6 7	10 11	15 16	23 24	34 35	52 53	⇩	
E	First	8	8												*	⇩	⇩	0 2	0 3	1 3	2 5	4 7	6 10	9 14	15 20	23 29			
	Second	8	16													⇩		1 2	3 4	4 5	6 7	10 11	15 16	23 24	34 35	52 53	⇩		
F	First	13	13											*	⇩		⇩	0 2	0 3	1 3	2 5	4 7	6 10	9 14					
	Second	13	26												⇩	⇩		1 2	3 4	4 5	6 7	10 11	15 16	23 24	⇩	⇩	⇩		
G	First	20	20										*	⇩		0 2	0 3	1 3	2 5	4 7	6 10	9 14							
	Second	20	40											⇩	⇩	1 2	3 4	4 5	6 7	10 11	15 16	23 24	⇩	⇩	⇩	⇩	⇩	⇩	
H	First	32	32									*	⇩		0 2	0 3	1 3	2 5	4 7	6 10	9 14								
	Second	32	64									⇩		⇩	1 2	3 4	4 5	6 7	10 11	15 16	23 24	⇩	⇩	⇩	⇩	⇩	⇩	⇩	
J	First	50	50								*	⇩	⇩	0 2	0 3	1 3	2 5	4 7	6 10	9 14									
	Second	50	100								⇩			1 2	3 4	4 5	6 7	10 11	15 16	23 24	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	
K	First	80	80							*	⇩	⇩	0 2	0 3	1 3	2 5	4 7	6 10	9 14										
	Second	80	160							⇩			1 2	3 4	4 5	6 7	10 11	15 16	23 24	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	
L	First	125	125						*	⇩	⇩	0 2	0 3	1 3	2 5	4 7	6 10	9 14											
	Second	125	250						⇩			1 2	3 4	4 5	6 7	10 11	15 16	23 24	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	
M	First	200	200					*	⇩	⇩	0 2	0 3	1 3	2 5	4 7	6 10	9 14												
	Second	200	400					⇩			1 2	3 4	4 5	6 7	10 11	15 16	23 24	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	
N	First	315	315				*	⇩	⇩	0 2	0 3	1 3	2 5	4 7	6 10	9 14													
	Second	315	630				⇩			1 2	3 4	4 5	6 7	10 11	15 16	23 24	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	
P	First	500	500			*		⇩	0 2	0 3	1 3	2 5	4 7	6 10	9 14														
	Second	500	1 000			⇩	⇩		1 2	3 4	4 5	6 7	10 11	15 16	23 24	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	
Q	First	800	800					0 2	0 3	1 3	2 5	4 7	6 10	9 14															
	Second	800	1 600		*	⇩	⇩	1 2	3 4	4 5	6 7	10 11	15 16	23 24	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	
R	First	1 250	1 250				0 2	0 3	1 3	2 5	4 7	6 10	9 14	⇧															
	Second	1 250	2 500	*	⇧	⇩	1 2	3 4	4 5	6 7	10 11	15 16	23 24		⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧
S	First	2 000	2 000			0 2																							
	Second	2 000	4 000			1 2																							

⇩ = Use the first sampling plan below the arrow. If sample size equals, or exceeds, lot size, carry out 100 % inspection.

⇧ = Use the first sampling plan above the arrow.

Ac = Acceptance number

Re = Rejection number

* = Use the corresponding single sampling plan (or alternatively use the double sampling plan below, where available).

Table 3-C — Double sampling plans for reduced inspection (Master table)

Sample size code letter	Sample	Sample size	Cumulative sample size	Acceptance quality limit, AQL, in percent nonconforming items and nonconformities per 100 items (reduced inspection)																												
				0,010	0,015	0,025	0,040	0,065	0,10	0,15	0,25	0,40	0,65	1,0	1,5	2,5	4,0	6,5	10	15	25	40	65	100	150	250	400	650	1 000
				Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re
A				⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	*	⇩	⇩	*	*	*	*	*	*	*	*	*	*	*	*
B				⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	*	⇧	⇩	⇩	*	*	*	*	*	*	*	*	*	*	*	*
C				⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇧	⇩	⇩	⇩	*	*	*	*	*	*	*	*	*	*	*	⇧
D	First	2	2	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	*	⇧	⇩	⇩	0 2	0 3	1 3	2 4	3 6	4 7	5 9	7 11	11 16	⇧	⇧	⇧	⇧	⇧
	Second	2	4	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	1 2	3 4	4 5	5 6	7 8	10 11	12 13	18 19	26 27	⇧	⇧	⇧	⇧	⇧
E	First	3	3	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	*	⇧	⇩	⇩	0 2	0 3	1 3	2 4	3 6	4 7	5 9	7 11	11 16	⇧	⇧	⇧	⇧	⇧	⇧
	Second	3	6	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	1 2	3 4	4 5	5 6	7 8	10 11	12 13	18 19	26 27	⇧	⇧	⇧	⇧	⇧	⇧
F	First	5	5	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	*	⇧	⇩	⇩	0 2	0 3	1 3	2 4	3 6	4 7	5 9	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧
	Second	5	10	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	1 2	3 4	4 5	5 6	7 8	10 11	12 13	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧
G	First	8	8	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	*	⇧	⇩	⇩	0 2	0 3	1 3	2 4	3 6	4 7	5 9	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧
	Second	8	16	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	1 2	3 4	4 5	5 6	7 8	10 11	12 13	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧
H	First	13	13	⇩	⇩	⇩	⇩	⇩	⇩	⇩	*	⇧	⇩	⇩	0 2	0 3	1 3	2 4	3 6	4 7	5 9	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧
	Second	13	26	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	1 2	3 4	4 5	5 6	7 8	10 11	12 13	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧
J	First	20	20	⇩	⇩	⇩	⇩	⇩	⇩	*	⇧	⇩	⇩	0 2	0 3	1 3	2 4	3 6	4 7	5 9	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧
	Second	20	40	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	1 2	3 4	4 5	5 6	7 8	10 11	12 13	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧
K	First	32	32	⇩	⇩	⇩	⇩	⇩	*	⇧	⇩	⇩	0 2	0 3	1 3	2 4	3 6	4 7	5 9	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧
	Second	32	64	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	1 2	3 4	4 5	5 6	7 8	10 11	12 13	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧
L	First	50	50	⇩	⇩	⇩	⇩	*	⇧	⇩	⇩	0 2	0 3	1 3	2 4	3 6	4 7	5 9	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧
	Second	50	100	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	1 2	3 4	4 5	5 6	7 8	10 11	12 13	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧
M	First	80	80	⇩	⇩	⇩	*	⇧	⇩	⇩	0 2	0 3	1 3	2 4	3 6	4 7	5 9	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧
	Second	80	160	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧
N	First	125	125	⇩	⇩	*	⇧	⇩	⇩	0 2	0 3	1 3	2 4	3 6	4 7	5 9	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧
	Second	125	250	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧
P	First	200	200	⇩	*	⇧	⇩	⇩	0 2	0 3	1 3	2 4	3 6	4 7	5 9	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧
	Second	200	400	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧
Q	First	315	315	*	⇧	⇧	⇩	0 2	0 3	1 3	2 4	3 6	4 7	5 9	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧
	Second	315	630	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧
R	First	500	500	⇧	⇧	⇧	0 2	0 3	1 3	2 4	3 6	4 7	5 9	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧
	Second	500	1 000	⇩	⇩	⇩	1 2	3 4	4 5	5 6	7 8	10 11	12 13	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧

⇩ = Use the first sampling plan below the arrow. If sample size equals, or exceeds, lot size, carry out 100 % inspection.

⇧ = Use the first sampling plan above the arrow.

Ac = Acceptance number

Re = Rejection number

* = Use the corresponding single sampling plan (or alternatively use the double sampling plan below, where available).

Table 8-A — Average outgoing quality limits for normal inspection (Single sampling plans)

Sample size code letter	Sample size	Acceptance quality limit, AQL, in percent nonconforming items and nonconformities per 100 items (normal inspection)																									
		0,010	0,015	0,025	0,040	0,065	0,10	0,15	0,25	0,40	0,65	1,0	1,5	2,5	4,0	6,5	10	15	25	40	65	100	150	250	400	650	1 000
A	2															18,4 14,8			42,0	68,6	97,1	158	224	326	470	733	1 085
B	3														12,3 10,5			28,0	45,7	64,7	106	149	218	313	489	723	1 102
C	5													7,36 6,70			16,8 16,0	27,4	38,8	63,4	89,4	131	188	293	434	661	
D	8												4,60 4,33			10,5 10,1	17,1 17,0	24,3	39,6	55,9	81,6	117	183	271	413		
E	13											2,83 2,73			6,46 6,32	10,5 10,5	14,9 15,1	24,4	34,4	50,2	72,3	113	167	254			
F	20										1,84 1,79			4,20 4,14	6,86 6,82	9,71 9,75	15,8 16,2	22,4	32,6	47,0	73,3						
G	32									1,15 1,13			2,62 2,60	4,28 4,27	6,07 6,08	9,90 10,0	14,0 14,3	20,4	29,4	45,8							
H	50								0,736 0,728			1,68 1,67	2,74 2,74	3,88 3,89	6,34 6,38	8,94 9,06	13,1 13,3	18,8	29,3								
J	80							0,460 0,457			1,05 1,05	1,71 1,71	2,43 2,43	3,96 3,98	5,59 5,63	8,16 8,27	11,7 12,0	18,3										
K	125						0,294 0,293			0,672 0,670	1,10 1,10	1,55 1,55	2,53 2,54	3,58 3,60	5,22 5,26	7,52 7,61	11,7 11,9											
L	200					0,184 0,183			0,420 0,419	0,686 0,685	0,971 0,971	1,58 1,59	2,24 2,24	3,26 3,28	4,70 4,73	7,33 7,41												
M	315				0,117 0,117			0,267 0,266	0,435 0,435	0,617 0,617	1,01 1,01	1,42 1,42	2,07 2,08	2,98 3,00	4,65 4,69													
N	500			0,0736 0,0735			0,168 0,168	0,274 0,274	0,388 0,388	0,634 0,634	0,894 0,895	1,31 1,31	1,88 1,89	2,93 2,94														
P	800		0,0460 0,0460			0,105 0,105	0,171 0,171	0,243 0,243	0,396 0,396	0,559 0,559	0,816 0,817	1,17 1,18	1,83 1,84														
Q	1 250	0,0294 0,0294			0,0672 0,0672	0,110 0,110	0,155 0,155	0,253 0,254	0,358 0,358	0,522 0,523	0,752 0,753	1,17 1,17															
R	2 000			0,0420 0,0420	0,0686 0,0686	0,0971 0,0971	0,158 0,158	0,224 0,224	0,326 0,327	0,470 0,470	0,733 0,734																

NOTE

Upper entries are for inspection for nonconformities per 100 items and are based on the Poisson distribution.
Lower entries are for inspection for percent nonconforming and are based on the binomial distribution.

Appendix 9: Endorsement of Manual by KPPRA, Khyber Pakhtunkhwa

KHYBER PAKHTUNKHWA
PUBLIC PROCUREMENT REGULATORY AUTHORITY
Add: 1st Floor, Directorate of Treasury & Accounts
Khyber Road Peshawar Ph: 091-9223462.

No. MD/KPPRA/Estt/ 2014-15
Dated: Peshawar the 05th August, 2014

To

The Director General Population Welfare,
Govt. Khyber Pakhtunkhwa.

Subject: **Finalization of Contraceptive Procurement Manual for the Department of Health and Population Welfare.**

Dear Sir,

I am directed to refer to your letter No. SOB(PWD) 2-3/CP/2014 Date May 14, 2014, on the subject cited above and to state that the Authority has reviewed the contraceptive Procurement Manual for Department of Health and Population Welfare, prepared with the technical assistance of USAID Deliver Project. The Document has been synchronized with Procurement Rules 2014 notified by Govt. of Khyber Pakhtunkhwa Finance Department vide No. SO(FR)/FD/9-7/2010/Vol-II, Dated Feb 03, 2014.

It is however added that during implementation / Enforcement of Procurement Manual, any issue arising thereof may be addressed in such a way that the objective of attaining a transparent procurement regime may be taken care of; please.

Yours faithfully,

(Muhammad Qasim)
Manager Enforcement

Copy to:-

1. Secretary Health, Health Dept. Govt. of Khyber Pakhtunkhwa.
2. Secretary Population Welfare Dept. Govt. of Khyber Pakhtunkhwa.
3. Director General Health Services, Govt. of Khyber Pakhtunkhwa.
4. Dr. Muhammad Tariq, Country Director, USAID Deliver Project, Islamabad.
5. Dr. Nadeem Akhtar Project Management Specialist Health USAID Pakistan.
6. Mr. Abbas Khan, Senior Provincial Logistics Manager USAID Deliver Project, Peshawar.
7. PS to Managing Director (KPPRA), Govt. of Khyber Pakhtunkhwa.

Manager Enforcement
(Muhammad Qasim)

Glossary of Definitions

Accountee	A legal term used in banking to describe the party (usually, the buyer) who is ultimately responsible for paying an amount guaranteed through a commercial "letter of credit."
Accrued	Accumulated through growth over time. For example, accrued penalties, accrued income.
Acceptable Quality Level (AQL)	A term used in quality assurance to classify defects into critical, major and minor categories.
Advising Bank	In documentary credits (L/Cs) - a commercial bank that notifies a beneficiary and/or transmits documents without taking on financial obligation.
Agent	A supply term for an independent contractor authorized by a manufacturer to promote and sell the manufacturer's products within a designated geographic area. Often an agent will contract to represent several manufacturers of non-competing products. Also used to describe an independent contractor or "agent" of an organization hired to inspect goods. Also, an independent contractor or "agent" hired to carry out procurement tasks.
Airway Bill	A shipping document issued by airlines and air-freight carriers when cargo is loaded on board an aircraft. It contains a description of the commodity being shipped, shipping instructions, terms and conditions of the shipment and applicable transportation charges.
Applicant	A legal term used in banking to describe a party (usually, the buyer) who is asking the bank to issue a commercial letter of credit in favour of a specified beneficiary (usually, the seller). Once the L/C has been issued, the "Applicant" becomes the "Accountee."
Arbitration	A process in which a disagreement between two or more parties is resolved by impartial individuals, called arbitrators, in order to avoid costly and lengthy litigation. The International Chamber of Commerce maintains a court of arbitration as do many individual countries.
Authorized Person	Any person who has been granted the power to authorize a transaction, or otherwise commit a Procuring Agency.
Award Notification	A notification from the purchaser to the successful bidder recommended for a contract (generally based on the lowest evaluated bid).
Batch	A manufacturing term meaning a single, uniform and homogeneous quantity produced from one compounding formulation, in one manufacturing and production operation and which has received entirely the same processing

	treatment. Used interchangeably with (manufacturing) Lot.
Batch Number	The identification number assigned to a manufactured batch. See Lot or Batch Number
Beneficiary	A legal term used in banking to describe the party who is entitled to collect funds guaranteed by a commercial letter of credit upon presentation of stipulated documents - usually shipping and quality assurance documents
Bid	A procurement term describing a written offer for a quantity of Goods, works or services at a stated price based on a technical specification and specific terms and conditions. Bids are submitted to an intending purchaser by an intending seller in response to an invitation to bid
Bidder	An intending seller or supplier who submits a bid offering goods or services in response to an invitation or request for bids and offers
Bid Documents	The papers constituting a bid. Requirements are specified by the intending purchaser
Bidding Documents	A written description and set of terms and conditions of an intended purchase that is circulated by the intending buyer to prospective sellers
Bid Offer	A procurement term meaning an offer for goods or services submitted or received in response to a specific Invitation to Bid
Bid Evaluation Committee	A committee established by an Authorized Person or by the Federal Procurement Cell of a ministry to undertake evaluation of bids and quotations for procurement
Bid Opening Committee	A committee established by an Authorized Person or by the Federal Procurement Cell of a ministry to undertake opening of bids and quotations for procurement
Bid Security	A financial instrument that is used to guarantee compensation to the prospective buyer for inconvenience and expense if a winning bidder rescinds his offer after the bid is closed and an award is made to him. Each bidder provides an amount stated in the bidding documents with their bid submission; bid security is refunded promptly to all losing bidders
Bill of Lading	A shipping document issued by a carrier (usually an ocean freight line) to a shipper that provides a written receipt for the goods, describes the conditions on which transport is made, and includes a written commitment to deliver goods at a stated destination to the lawful holder of the bill of lading
Boat Note	Report of a marine insurance survey conducted on board an incoming ship to assess the loss or damage of a consignment
Boilerplate	A selected text or part of a document that is repeatedly used without change
Buffer Stock	A term used in supply systems to describe extra quantities of stock kept on hand to cover unanticipated shortages - 25 % above expected usage is common
Buyer	Party to a purchase transaction who pays a seller in exchange for goods. The Buyer does not necessarily have to be the recipient or consignee of the goods.

C&F Agent	A licensed professional agent appointed by an importer to clear its consignment from port and customs authority coming from abroad
Carrier [carriage]	Any person who, in a contract of carriage, undertakes to perform or to procure the performance of carriage by rail, road, sea, air, inland waterway or by a combination of such modes
Census Data	Statistics gathered about individuals in a national population; primarily numbers. Used by public health programs to estimate annual commodity requirements and thus, determine the quantities that need to be purchased to meet these requirements
Certificate of Free Sale	See "Lot Release Certificate."
Certificate of Inspection	A document often required with shipments of perishable or other goods; certification attests to the good condition of the merchandise immediately prior to shipment
Certificate of No Objection	See No Objection Certificate
Certificate of Origin	A shipping document certifying that the goods in a shipment have been produced in the stated country of origin
Claim Bill	A bill prepared by an insured to lodge its claim for compensation
Clean Report of Findings	A certificate issued by an inspection company stating that no discrepancies were found between specified criteria and the product as prepared for shipment. Pre-shipment inspection at the manufacturer's facility is recommended for most health sector goods. Some countries require routine (cursory) visual inspections at the port of loading for all goods entering the country
Coercive Practice	Impairing or harming, or threatening to impair or harm, directly or indirectly, any party or the property of the party to improperly influence the actions of the party
Cold Chain	A system of maintaining perishable medicines and vaccines at low temperatures from the time of manufacture until given to a child or adult. All vaccines and some medicines are sensitive to too much heat and some are sensitive to freezing
Collateralize	A banking term meaning that money (or other security) is deposited or otherwise made available to cover a future payment. For example, letters of credit must be "collateralized."
Collusive Practice	An arrangement between two or more parties designed to achieve an improper purpose, including to influence improperly the actions of another party
Commercial Bank	A "for profit" bank that provides services to the public.
Commercial Invoice	A shipping document issued by the seller, that identifies the buyer, and provides a description of the goods, the agreed price, delivery and payment terms, shipping date, mode of transport and an assigned invoice number

Commodity	Commonly used to describe consumable products
Competitive Bidding	Procurement process in which clearly stated product specifications and contract requirements are issued to multiple suppliers to solicit pricing and performance responses (bids). The purpose is to generate competition among several suppliers, which theoretically elicits the lowest possible prices. There are several types of competitive bidding procedures, including International Competitive Bidding, Local Competitive Bidding and Limited Competitive Bidding, Request for Quotation
Conditional Discount; Cross Discount	A discount sometimes offered by potential suppliers bidding on two or more contracts simultaneously to apply only if two or more contracts would be awarded to him
Consignee	A term used in shipping that describes the party to whom something is entrusted, e.g., the "ship-to" party
Confirming Bank	In documentary credits (L/Cs) - a commercial bank that promises to pay the beneficiary if the issuing bank defaults
Consignment	A shipment containing part or whole of the contracted quantity of [imported] goods
Context	Circumstances that surround and influence. As in program context, market context
Contract	An agreement entered into by two parties for the execution of certain activity, e.g., sale and purchase, construction, providing services, etc.
Contractor	A party having entered into a contract with the purchaser for supplying certain goods or performing certain works or providing certain services
Convertible Currency	Currency that can be quickly bought and sold for other currencies; commonly traded internationally
Correspondent Relationship	The relationship between two banks when they have formally agreed to perform services for each other
Corrupt Practice	Offering, giving, receiving or soliciting, directly or indirectly, anything of value to influence improperly the actions of another party
Coverage	A health sector program term for the estimated number of individuals actually served as a percentage of the target population
Criteria	Specific points, standards, qualities, requirements against which something is judged
Debarment	Shut out, exclude or prohibit [a firm] from participating in future competition for contracts
Defects - Critical, Major, Minor	Quality assurance terms used in evaluating a product's appearance, packaging and packing through visual examination and comparison with a precise description of requirements; results in a classification of any defects according to importance. There are published standards for how many defects can be allowed in a particular lot size under different assumptions. Used

	in condom procurement
Defect, critical	A defect which, according to experience and professional criteria, makes a product dangerous or not viable for its intended use
Defect, major	A defect that may make the product more difficult to use but does not have the safety and efficacy risk associated with a critical defect
Defect, minor	A defect that is unlikely to affect usability but represents a departure from the specifications
Determination	A decision that has been reached. For example, World Bank's no objection determination based on a review of draft bidding documents
Demurrage Charges	Charges assessed against the consignee by a carrier, shipping agent or customs agent for delay beyond the time allowed or agreed upon for unloading and/or removal of goods from port facilities
Development Partner	Financing institutions extending credits for development programs of the government; in respect of HPSP, it is the World Bank (International Development Association)
Direct Contracting	A procurement method in which price and terms are settled with one chosen supplier without asking others for bids (e.g. without competition).
Direct Purchase	Used by the World Bank to mean purchase from a pre-selected source without competition, for example, when there is only one manufacturer of a required product. Sometimes used in government health programs to mean purchasing vaccine and contraceptives directly from a manufacturer rather than through UNICEF or another third party
Discrepancies	Used in banking and trade to mean lack of agreement with stated requirements and/or documents
Documentary Evidence	Being, consisting of, or contained exclusively in documents
Domestic Preference Allowance	A term used in World Bank procurement documents to describe a competitive advantage, expressed in a percentage, which is sometimes given to local manufacturers of goods competing for contracts against international sources
Drug Formulary	A sub-set of "essential drugs" keyed to specific levels of health care [facility].
Duties	A tax charged by a government, especially on imports
Eligibility (criteria)	Not excluded from competing for contracts in general by reason of nationality, debarment, lack of regulatory approval, etc
Entity	A business and legal term to describe something that exists and functions as a separate and distinct body, for example, a corporation, a ministry of health, a committee

Eligible Bid	A Bid that meets the basic eligibility criteria in a preliminary screening and which then goes forward for evaluation. Mandatory eligibility criteria may include registration as a company, possession of a business license etc. A Bid may also specify that a Bid Security for a specified amount and in a specified format be enclosed with the tender. If there is no Bid Security, the bid is "non-compliant" and, therefore, not "eligible" to go forward to the evaluation stage
Essential Drugs [List]	A model list of around 300 drugs that provide for the health needs of the majority of the population
Estimate of Procurement Requirements	A judgment or approximate calculation of future commodity needs; quantification based on a forecast of use plus buffer stock requirements less existing stock and undelivered purchases
Evaluated Cost	An offered price adjusted for corrections, discounts, domestic preference and usage factors
Evaluation Criteria	Basis for judgment [announced in bidding documents] that will be used to select the winning bidder
Expiry Date	A supply term for a date established by the manufacturer that appears on a drug, contraceptive or vaccine, beyond which the manufacturer will not guarantee the potency, purity, uniformity or bio-availability of the product
Financial Instrument	A legal document that conveys financial commitment, such as a bond.
Financial Powers	The authority to spend given to an officer in the performance of his duties. In most Government systems, the amount of expenditure an officer may authorize is usually related to the level of his responsibility as well as to his seniority
Forecast	A term used in public health programs to describe a rational projection of future commodity demand based on population, birth rate and past consumption data
Force Majeure	An event or affect that cannot be reasonably anticipated or controlled
Fraudulent Practice	Any act or omission, including a misrepresentation, that knowingly or recklessly misleads, or attempts to mislead, a party to obtain a financial or other benefit or to avoid an obligation
Generic	Applicable to all of a kind; common, not protected by trademark or patent. Used extensively in drugs procurement
General Procurement Notice	Annual notice placed in UN publication Development Business about scope of anticipated ICB procurement to be financed by World Bank loans, amount and purpose of loans, and name and address of Borrower's agency responsible for procurement
Specific Procurement Notice	Invitations to bid (or pre-qualify) for specific contracts advertised in newspapers, etc
Good Manufacturing Practice (GMP	An organized set of activities and performance standards covering personnel, premises and equipment, animal quarters and care, production, labeling, lot processing records and distribution records, quality assurance and quality

	control. A facility where GMP is followed can be relied upon to consistently produce good quality products that conform to established specifications because it maintains high standards of performance and adheres to written procedures. Used mainly in pharmaceutical, vaccine and medical device production
Guarantor	A person or firm that guarantees to pay for someone else's debt if he or she should default on a loan or other financial obligation
Harmonized Tariff System (HTS) Code	An international codification of merchandise for the purpose of classifying goods for tariffs and customs. The HTS assigns a 6-digit code for general categories of goods. Countries that use the HTS are allowed to define commodities at a more detailed level than 6 digits, but all definitions must be within that 6-digit framework
Implementation Reqmt	Defined procedures and milestones associated with a project
Implementing Agency	The agency responsible for carrying out project activities and monitoring progress toward defined milestones, goals and objectives
INCOTERMS	International rules for the interpretation of the most commonly used terms in foreign trade published by the International Chamber of Commerce (ICC).
Indent	Request from the end-user for certain goods works or services that are to be purchased
Inspection Agent	A party (or organization) appointed by the purchaser to conduct inspection of certain goods works or services
Inspection Criteria	A term for the instructions and specifications against which an inspection agent will examine a shipment, usually before it leaves the manufacturer's site
Inter-lineation	Notations written between the lines [of original bidding documents]
International Chamber of Commerce (ICC)	A non-governmental organization that serves world business by harmonizing trade practices, formulating terminology and establishing guidelines for importers and exporters
International Competitive Bidding (ICB)	A procurement method that is initiated with a widely advertised notice of the bidding opportunity. Sealed bids are required based on clearly stated product specifications and performance expectations. Submissions are evaluated on their technical, commercial, contractual and financial merit, with awards going to the supplier making the most advantageous and cost-effective offer. All bids are final and no negotiation is allowed, except in regard to minor contractual points, after selection of a winning bid. The objective of the ICB is to provide all eligible prospective bidders with an equal opportunity to participate in the competition. Also known as open, or unrestricted, bidding
International Shopping	A term used by the World Bank and others to describe a procurement process that relies on informal quotations and catalogue pricing to establish a minimum level of competition. See Request for Quotation

Inventory	Stock of goods available in a store or warehouse or go-down on a particular date
Invoice	A document showing a short description of the cargo and its unit and total price; see "commercial invoice"
Joint Venture	A business enterprise in which two or more companies enter a temporary partnership
Labeling	Used in the context of pharmaceuticals, vaccines and contraceptives to describe written text on packaging, boxes and accompanying leaflets. For products that are regulated by a government authority, labeling is considered an important part of the product and changes must be approved
Lead Time	The time interval needed to complete a procurement cycle. It begins when the need for new stock is recognized and ends when that stock is received and available for issue. Alternate definition: Time from order to delivery; e.g., manufacturing and shipping time.
Letter of Commitment	An instrument committing funds for payment to a supplier against a contract
Letter of Intent	A written expression of the purchaser made to the supplier to issue an award in favour of the supplier
Letter of Credit	An arrangement by banks for settling commercial transactions; specifically, a written promise by a bank given to the Seller in accordance with the instructions (and cash deposit) of the Buyer to pay up to a given sum of money within a prescribed time limit when and if the Seller presents specified documents that give evidence of his performance
Licensed Product	In the context of pharmaceuticals, vaccines and contraceptives, licensing by the regulatory authority of both the importing and exporting country implies a quality standard based on verified Good Manufacturing Practices, quality assurance data and appropriate oversight
Liquidated Damages	In sales contracts, specified sum to be paid to the purchaser should the seller default on its obligation (usually pertaining to a delivery schedule).
Limited International Bidding (LIB)	A procurement term describing the bidding process that limits participation to international and domestic suppliers that have been pre-qualified, pre-selected or short-listed in some manner by the purchaser. See Restricted bid and Pre-qualification
Lot	A supply term that can be used in two ways: Production Lot (see Batch-manufacturing) and Shipping Lot
Lot or Batch Number	A manufacturing term that describes the series of numbers or letters or both established to record production and control of a single, uniform and homogeneous quantity of drugs, chemicals or biologicals produced from one formulation, in one manufacturing and production operation and which has received entirely the same processing treatment
Lot Release Certificate	A regulatory term describing a certificate issued by the National Regulatory Authority of the country of manufacture that states the (manufacturing) lot number being shipped has been tested by the government's laboratory or

	checked in some other manner and found to be in conformity with the regulations of the country of manufacture and is released for sale. In some cases, this document may be titled "Certificate of Free Sale".
Lowest Evaluated Bid	A bid (i) most closely conforming to evaluation criteria and other conditions specified in the bidding document; and (ii) having lowest evaluated cost.
Manufacturer's Representative	A direct employee of a manufacturer with responsibility to promote the use of, provide information on and sell the manufacturer's products. In some cases, the representative also facilitates importation. Sometimes the term "agent" is used to convey the same relationship.
Margin of Preference	See "Domestic Preference".
Marking	Used in packing and shipping for the application of numbers, letters, labels, tags, symbols or colors for handling and identification during shipment and storage.
Material Deviation	Used in evaluating bids to describe a significant and unacceptable difference from the requirements stated in bidding documents. More precisely, a material deviation is one that affects, in any way, the price, quantity, quality or delivery of the goods as required in the bid documents, or limits in any way the responsibilities, duties or liabilities of the bidder or any rights of the purchaser.
Merit Point System	A numerical system used to evaluate and compare offers or bids. Points (based on a total of 100) are assigned according to how well an offer is judged to match evaluation criteria and preferences (which are stated by the purchaser in the original bidding documents) and its relative standing in the range of prices offered.
Middleman	An independent broker who purchases product from a manufacturer or wholesaler and resells the product. This adds to the final cost of the product because the middleman's revenue from the transaction is the difference between his acquisition and holding cost and his sales price. Purchase of vaccine, pharmaceuticals and contraceptives through middlemen can increase the risk of receiving poor quality, mishandled or counterfeit product unless shipments are made directly from the manufacturer to the purchaser with appropriate original documentation.
National Competitive Bidding (NCB)	A procurement method that follows the same format as International Competitive Bidding, but limited to local participants.
National Control Authority (NCA)	See National Regulatory Authority. Both terms are currently in use.
National Control Laboratory (NCL)	A laboratory advisory to the National Control Authority.
National Dailies	Widely circulated daily newspapers whether in the native language or otherwise.
National Regulatory Authority (NRA)	An independent government entity responsible for establishing procedures to ensure that medicines (and biological products) intended for use in the country are

	safe, potent and effective.
Negotiated (Document)	Term used in international trade meaning that title to the Goods has been transferred to a new owner by delivery; normally requires transfer of funds from buyer to seller as well.
Negotiable Shipping Document	A document that establishes ownership of Goods and, therefore, has monetary value; usually, an ocean Bill of Lading
Non-Governmental Organization	Organization that is not part of the structure of a government, but may perform complementary activities
Non-responsive	Does not meet basic requirements; for bids this would include such critical items as signatures, bid security, completeness, agreement to terms and conditions, etc.
No Objection Certificate	A shipping/import document sometimes required by a country's customs, tax or other laws certifying that domestic manufacturers of pharmaceuticals, biologicals and medical devices have "no objection" to the import of a competing, similar or identical product.
No Objection Determination	A term used in World Bank procurement to describe the Bank's approval of draft bidding documents and recommendation for award.
Obstructive Practice	Deliberately destroying, falsifying, altering concealing of evidence material to the investigation or making false statements to investigators in order to materially impede an investigation into allegations.
Offer	Used interchangeably with "bid" and "proposal".
Open Bid	A formal procurement procedure in which bids are accepted from any interested local or international source of the required product.
Packaging	A product's primary containers and coverings. In the context of injectables, vials and ampoules are the primary packaging, while boxes and bags containing several, up to 100, vials or ampoules are secondary packaging. In the context of tablets, blister packs or tins may be the primary packaging.
Packaging for bidding	A term used by the World Bank and others for organizing very large, diverse schedules of goods to be purchased into groupings of like-items for bidding purposes.
Packing	Assembling of items into a unit for shipment; carton, over-wrapping and insulation for protecting products against damage or deterioration during shipment.
Packing Requirements	Identifies how product should be packed to withstand the handling and climatic conditions it will be subject to during transit. For heat sensitive pharmaceuticals and vaccines this includes instructions on the specific temperature range in which the product must ship and whether it can or cannot be frozen as well as information on the type of packaging and strength of packaging material to be used and inclusion of cold chain monitoring devices.
Packing List	A schedule showing detailed packing information including: items and totals, number of units or items per box or crate, total number of boxes or crates with

	individual identification numbers thereof, shipping marks, total volume of the cargo, weights and dimensions per box or crate, etc.
Patent	Exclusive rights granted by a government to an inventor to manufacture, use, or sell an invention for a certain number of years. US drug patents are usually good for 17 years.
Payment Terms	A description of how, where and when payment will be made; for example, Letter of Credit, Cash in Advance, Open Account.
Performance Security	A procurement term describing the financial instrument used to guarantee compensation to the Buyer for inconvenience and expense if the Seller does not perform, i.e., does not produce and ship the contracted goods or provide the contracted services within the stated period. The Seller puts up his own funds, often through a bank or an insurance company, to be held in reserve until the contract terms have been met.
Pharmacopoeia	A book published usually under the jurisdiction of the government and containing a list of drugs, their formulas and methods for making medicinal preparations, requirements and tests for their strength and purity and other related information.
Port of Entry	The port (including airport and land-port) designated in the bid and mentioned in the Bill of Lading or AWB where the consignment(s) under a contract is (are) to be carried to.
Port of Loading	The port (including airport and land-port) designated in the bid and mentioned in the B/L or AWB where the consignment is loaded into the ship for onward transportation to the Port of Entry.
Pre-qualification (of supplier)	A process of pre-approving suppliers for participation in bids based on a judgment of reliability, technical competence and financial stability.
Pre-qualification (of product)	A process of pre-determining that a specific product (usually a pharmaceutical or vaccine) of a specific manufacturer meets stated requirements and may be considered for purchase contracts in the approving country. Licensing by the National Regulatory Authority in the purchasing country automatically confers pre-qualification status.
Pre-shipment Inspection	Inspection of the contracted goods by or on behalf of the purchaser to ensure its conformity to the bid specification; this is done at the premises of the supplier or manufacturer prior to the goods being shipped.
Prior Review	World Bank terminology for its right to review and approve certain procurement decisions of a borrower before they are acted upon.
Procurement	The formal process of acquisition of goods, works, or services.
Procurement Agent	An individual or organization paid to act on behalf of a purchaser.
Procurement Entity	Body functioning as the purchaser in a commercial transaction (see entity, above).
Procurement Package	Goods of a similar nature that have been grouped together for procurement under a single contract in the interest of efficiency.

Procurement Plan	Package-wise schedule for purchasing activities including description of goods to be purchased, budget amount & source of funds; time period in which goods will be procured and the method of procurement; separate from "Operational Plan".
Procurement Requirements	A complete description of the product to be purchased, including technical attributes (especially manufacturing and quality assurance norms), program specifications (including packaging, packing), shipping terms, payment terms, port of delivery, delivery date, quantity, documentation and any other relevant detail of the expected purchase.
Procurement Transaction	Agreements and actions of a Buyer and a Seller around a specific purchase; usually documented and legally binding.
Procurement Unit	The officer or team designated by a Procuring Agency to conduct procurement on its behalf.
Procuring Agency	Program with responsibility to undertake procurement.
Performa Invoice	An abbreviated invoice prepared by a supplier in advance of a sale or shipment. It gives a close approximation of weight and value of the shipment and other relevant data. Performa invoices are used in some international procurement situations to support the purchaser's request to government authorities for import permits and foreign exchange. It is not binding on the seller until the order is confirmed.
Proposal	A procurement term that describes an offer to supply goods or services that is made in response to a specific Request for Proposal (RFP). Less formal in structure and process than sealed bidding (ICB, NCB, and LIB).
Proprietary Goods	Goods manufactured and sold only by a particular firm, usually under patent.
Protocol	A term used to describe a formal plan and specific methods for inspecting and testing goods.
Public Fund	As defined in SRO XXII of 2002, Chapter I, Section 2, Sub-section (k).
Public Procurement Regulatory Authority	An autonomous body responsible for prescribing regulations and procedures for public procurements by the ProvincialGovernment owned public sector organizations with a view to improve governance, management, transparency, accountability and quality of public procurement of goods, works and services.
Public Sector Supply Service	An organization that contracts annually with manufacturers for large quantities of product which it then supplies in smaller quantities to individual clients in the public sector on a reimbursable, but non-profit basis. UNICEF and UNFPA are examples.
Pull System	A term used in distribution systems to indicate that peripheral levels request deliveries of specific kinds and amounts from a central level.
Procurement Office	The offices that will undertake and accomplish the task of procurement of

	goods under the HPSP.
Push System	A term used in distribution systems to indicate that a central authority is sending goods to lower levels based on its own calculations of need rather than specific requests from the lower levels, i.e., it "pushes" goods to the lower levels.
Qualification (criteria)	An attribute that must be met or complied with that fits a competing firm for performing a specific contract.
Qualified Remarks	In international shipping, written list of deficiencies or damage noted by inspecting agent.
Quality Assurance	The combination of organized activities performed to demonstrate that a product meets quality criteria and specifications for its intended application. Quality assurance within the manufacturing organization provides confidence to the management. Quality assurance outside of the manufacturing organization provides confidence to the purchaser. In the context of pharmaceuticals, vaccine and contraceptives, it is typically undertaken before a shipment leaves the manufacturer's facility and/or, before the product is released for use in a country.
Quality Control	A manufacturing term that describes internal operational techniques and activities aimed at monitoring the manufacturing process and eliminating causes of unsatisfactory performance. Some quality control and quality assurance actions are interrelated.
Registration	A term used in regulating pharmaceuticals and vaccine; exact usage varies from country to country. It is often synonymous with Licensing but it can mean simply that the particulars about a shipment are recorded as it enters a country.
Request for Proposal	The term commonly used for bidding documents in the procurement of consultancy services.
Responsive Bid	A Bid that meets the technical requirements of the bidding document in the evaluation stage. Technically non-responsive bids do not go forward to the financial evaluation stage.
Reservations (to)	Negative findings, exceptions, disagreement, lack of approval.
Restricted Bidding	Bid procedures other than Open Competitive Bidding. Restricted Bidding refers to Bidding based on a shortlist of suppliers, on pre-qualification or on the various methods of procurement concerned with sole suppliers or a limited number of suppliers.
Retention Money	A certain percentage of the bill money payable to a contractor for the contracted goods works or services, that is held back retained by the purchaser, and paid after fulfillment of certain obligations by the contractor.
Revenue Funds, Budget	Funds, budget derived from a government's own activities [usually tax collection] rather than from development loans or grants such as HNPSP.
Safeguard	Protect, guard, keep safe.
Sampling	The process of selecting a small, representative quantity of materials from a much larger batch, shipment or consignment. Inspecting this representative sample

	enables judgment about the quality of the entire batch or shipment of products without having to inspect each individual unit.
Schedule of Requirements	Part of a bidding document that describes the quantity of goods and expected delivery time.
Sealed Bids	A procurement process where formal bids are submitted in sealed envelopes and held unopened until an appointed date and time, then opened and read out in public with bidders in attendance. See International Competitive Bidding, Local Competitive Bidding, Limited International Bidding.
Securities	Something given or deposited as surety for the fulfillment of a promise or an obligation, the payment of a debt, etc.
Seller	The party to a contract who offers goods, commits to seeing that they come into the Buyer's possession and (usually) receives payment from the Buyer. The Seller does not necessarily have to be the Supplier of the goods.
Shelf Life	The length of time designated by the manufacturer that a product may be stored without affecting its usability. Shelf life varies from product to product. The shelf life for a drug varies from 3-5 years. After the expiry date, the potency, purity and "bio-availability" of active ingredients are not guaranteed and drugs must be discarded and destroyed.
Shipping Marks	A mark or writing inscription that the purchaser instructs the seller to paint or write visibly and legibly on the outer side(s) of the boxes or crates so that the purchaser's goods can be easily seen and identified; usually this is instructed in the bidding document.
Shipping Terms	A description of how goods will be shipped, who is responsible for them at each stage of the process and who pays which costs. See INCOTERMS.
Short List	In procurement, a list of potential suppliers or contractors who have been qualified approved or pre-selected in some manner.
Sole Source	A procurement term used to describe purchasing from a single manufacturer without competition among potential suppliers; most often applies to items that are not available from any other source. Also see Direct Procurement.
Solicitation	A procurement term for the process of inviting bids or requesting proposals for the supply of a product or service; also used to refer to the document requesting bids or proposals.
Specification	Detailed, precise written description.
Specification Committee	A committee formed by an Authorized Person, Relevant Authority or a Federal Procurement Cell to undertake the preparation of specifications and documents for procurement
Standard	Something that is established by authority as a rule for the measure of a quantity, weight, extent, value or quality. For example, the International Standards Organization (ISO) establishes "rules" for the vial closures commonly used for injectables.
Substantially	In World Bank procurement, a bid that contains no material deviations from or

Responsive	reservations to the terms, conditions and specifications in the bidding documents
Supplier	The party who transfers goods out of his own control to a named recipient.
Surety	A person or firm that is legally responsible for the debt, default or delinquency of another.
Survey Report	A report of the insurance survey.
Target Population	A program term for the total number of intended clients based on expected coverage rates
Technical Evaluation Committee	A committee established to assist a Procurement Unit, Committee Relevant Authority, Bid Evaluation Committee or a Federal Procurement Cell to review documents and make technical evaluations
Threshold Level	A threshold is a point of entry or beginning. In World Bank terminology, it is a monetary level that determines whether a particular contract should be reviewed by World Bank prior to being invited and executed, and which government committee is responsible for bid evaluation; these levels are set in the loan or development credit agreement.
Trademark	A name, symbol, figure, letter, word or mark adopted and used by a manufacturer or merchant in order to designate his or her goods and to distinguish them from those manufactured or sold by others. Trademarks must be registered with a patent and trademark office to assure exclusive use by their owners.
Transparency	Openness and accountability in all activities and actions concerned with procurement.
Turnover	The number of times a particular stock of goods is sold and restocked during a given period of time; the amount of business transacted during a given period of time.
Uniform Customs and Practice for Documentary Credits (UCP)	A set of rules for cross-border transactions relating to Letters of Credit (also known as Documentary Credits and Documentary Letters of Credit) codified by the International Chamber of Commerce (ICC).
Unresponsive Bid	A procurement term used describe an offer that does not comply with the most basic instructions and requirements stated in the bidding documents provided by the purchasing organization. For example, an unresponsive bid may be one that is not signed, is in the wrong language or does not offer the required product(s).
Weighting (Factor)	A system of units in a scale measuring weight (or value). In procurement, used to assign values to non-monetary items prior to comparing bids.
Wholesaler	A supply term for a dealer who purchases supplies from a manufacturer on his own behalf and resells them for a profit.
Work Order	Purchaser's communication to a contractor instructing him to undertake the obligations of a contract; usually a work order is part of the contract.

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