Contraceptive Procurement Manual

Health and Population Welfare Departments,
Government of Sindh

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Abstract
The Sindh Public Procurement Regulatory Authority (SPPRA) team has examined the manual carefully and made every effort to synchronize this manual with Sindh *Public Procurement Rules (SPPR), 2010–Amended 2013*, regulations, standard bidding documents (SBDs), and policy instructions issued from time-to-time. However, if any provisions or the interpretation of SPP rules, regulations etc., cited in this manual conflict with the *SPP Rules, 2010–Amended, 2013*, regulations, SBDs and/or policy instruction issued by the Authority from time-to-time, the *SPPR, 2010–Amended, 2013*, 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
CDVAT	Customs Duty and Value Added Tax
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
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
NRA	National Regulatory Authority
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
SPPR	Sindh Public Procurement Rules
SPPRA	Sindh Public Procurement Regulatory Authority
UNFPA	United Nations Population Fund
UNICEF	United Nations Children's Fund

U.S.	United States
VAT	value-added tax
WHO	World Health Organization

Acknowledgments

The *Contraceptives Procurement Manual* of Sindhwas developed with the support of all relevant public sector stakeholders, including the Sindh 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 thismanual.

Wesincerely appreciate the valuable support extended by USAID | Pakistan to strengthenthe health sector of the Sindh province. We wish to thank Mr. Randolph Augustin, Director,HealthOffice.USAID | Pakistan, for hisleadership and coordinated support for the USAID | DELIVER PROJECT as they successfully developed this manual.

We also wish to express our appreciation forthe 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 Sindh, 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 Sindh Public Procurement Regulatory Authority (SPPRA), 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 Sindh, to ensure that it meets their requirements and needs. The manual completely complies with the Sindh Public Procurement Rules of 2010–Amended 2013; SPPRA 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 Sindh have easy access to quality contraceptive products, enabling them to have healthy timing and spacing of pregnancy.

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Introduction

The *Contraceptives Procurement Manual* offers valuable information for the procurement personnel of both the Health and Population Welfare Departments, Government of Sindh, about the guidelines that are required when procuring contraceptives of good quality in the international market; this aligns with the Sindh government's effort to meet the desired goals in maternal and child health within the province. The manual incorporates the best international procurement practices, promoting and encouraging transparency, accountability, and efficiency during public sector procurement. In this manual, the key phases of the procurement cycle are explained at length—procurement planning, issuing invitations to bid, bid evaluation, supplier selection, contract award, and management.

The primary audience for the *Contraceptives Procurement Manual* comprises procurement officers and other direct procurement staff who are responsible for procuring quality contraceptives. The manual includes 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—including information on pre-qualification and pre-shipment compliance programs—which procurement officers need to effectively implement the public sector procurement of contraceptives.

The *Contraceptives Procurement Manual* also provides pertinent information for policymakers and mid-level decisionmakers who do not need a detailed understanding of the procurement process, but who would find a basic understanding helpful to ensure the effective implementation of procurement process. For this purpose, the audience review of appendix 4: Summary Guide for Policymakers, Directors, and Managers is recommended.

The *Contraceptives Procurement Manual* also includes key reference documents, such as the Sindh Public Procurement Rules (SPPR), 2010-Amended 2013 and the Drugs (Labeling and Packing) Rules 1986, to ensure that procurement officers have easy access to the original resource documents when they prepare for and conduct public sector procurement of contraceptives.

To fully understand the breadth and scope of the information it contains, the users of the *Contraceptives Procurement Manual* are encouraged to review the manual thoroughly which will helpthem to conduct effective public sector procurement of quality contraceptives for the people of Sindh.

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 Sindh's Public Procurement Rules (SPPR) 2010–*Amended 2013* are based on well-established and widely accepted principles of public sector procurement:

Economy, Efficiency, Equality, Fairness, Transparency

Properly administered, open competition (competitive bidding) fulfills these requirements; it is also the underlying philosophy of good public sector procurement.

C. Principles of Competitive Bidding

1. Suitable Package

Design bid requirements should 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 45 days to submit offers *(Rule 18 of SPPR, 2010–Amended 2013).*

3. Nondiscrimination

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 defined by the Sindh Public Procurement (*Rules 17,21and 44of SPPR, 2010–Amended 2013*).

4. Accessibility

Allow wide access to competition by setting reasonable costs for bidding documents and securities; respond 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; include the phrase *or equivalent* if a brand name, trademark, or catalog number must be used *(Rule 13 of SPPR, 2010–Amended 2013).*

6. Formality

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

7. Confidentiality

Do not open the bids before the assigned date and time *(Rule 41 of SPPR, 2010–Amended 2013).* 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 (*Rule 42 of SPPR, 2010–Amended 2013*). Do not ask or permit any bidders to change their bid after the deadline for submission. Bidders can only be asked for clarification needed to evaluate their bid, but it cannot change the substance of the bid *(Rule 43 of SPPR, 2010–Amended 2013).*

9. Objectivity

Determine if each bid is *substantially responsive* by checking for errors, correct signatures, inclusion of all required documents, and adherence to the 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.

Rule 52 of SPPR, 2010–Amended 2013 states—

Save as otherwise provided there shall be no negotiations with the bidder having submitted the lowest evaluated bid or with any other bidder."

D. Procurement Policy Guidelines

The Government of Sindh has established clear procurement rules (*SPPR, 2010–Amended 2013*) 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 *SPPR, 2010–Amended 2013*. In addition, the latest information can be found on the Sindh Public Procurement Regulatory Authority (SPPRA) website at http://pprasindh.gov.pk.

E. Procurement Methods—Goods

The Government of Sindh, when purchasing entities, requires that the most appropriate method of procurement be used for a specific purpose. The GOS 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 25,000 rupees simplified petty purchase procedures can be followed; but, for procurements with an estimated cost equivalent to U.S.$10 million or above, the more complex and documented international competitive bidding procedures is the default method of procurement *Rule 15 (2)(a)(ii) of SPPR, 2010–Amended 2013*. 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 SPPRA website, the procuring agency's website, and other internationally recognized procurement advertisement websites. All suppliers are invited to participate in the bidding process—*Rule 15 (2)(a) and Rule 21 (4) of SPPR, 2010 –Amended 2013*.

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

2. Prequalification of Bidders

Rule 27 of *SPPR, 2010–Amended 2013* 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 27 of SPPR, 2010–Amended 2013*(see appendix 1).

See appendix 6for 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 *SPPR, 2010–Amended 2013*; procedures are described in *Rule 15 (b) of SPPR, 2010–Amended 2013*.

4. Request for Quotation (RFQ)

*Rule 16(1)(a) of SPPR, 2010–Amended 2013*allows RFQs to be issued for procurement action that is less than 100,000 rupees 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. 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 16(1) (b) of SPPR, 2010–Amended 2013*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.

6. Petty Purchases

This method is allowed by *Rule 16 (1)(d) of SPPR, 2010–Amended 2013*for goods with a value of less than 25,000 rupees. Petty purchases are exempt from the requirements of bidding or the quotation of prices.

F. Rules and Tools for Procurement of Goods/Contraceptives

1. Rules for Procurement of Goods

a. Sindh Public Procurement Rules 2010–Amended 2013

The Sindh Procurement Regulatory Authority, Government of Sindh, has developed and adopted a set of procurement rules—*Sindh Public Procurement Rules, 2010–Amended 2013*—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.

SPPR, 2010—Amended 2013 covers the organization of public procurement, basic procurement rules, and a choice of procurement methods. Procurement detail is based on National OCB. In addition, *Rule 31* and *Rule 32* describe the process for complaints and appeals.

b. 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 Goods/Contraceptives

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

a. Government of Sindh Standard Bidding Documents

The Department of Health (DoH) Sindh 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

When procuring entities, *Rule 11 of SPPR, 2010–Amended 2013*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 Sindh, 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 give potential suppliers an accurate, complete picture of what is required. They are written in the technical terms that correspond to the relevant industry; they also 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 catalog numbers, and they describe requirements in generic terms. If alternative sets of standard accessories are available, the specifications clearly indicate the choices. Under the bidding format used by both the Government of Sindh and the World Bank, the purchasing entity must provide technical specifications. Later, the formal specifications will become part of the contract between the buyer and the seller. See module 1 and module 2 for more information. In addition, the draft bidding documents for the procurement of contraceptives, in appendix 3, provide 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.

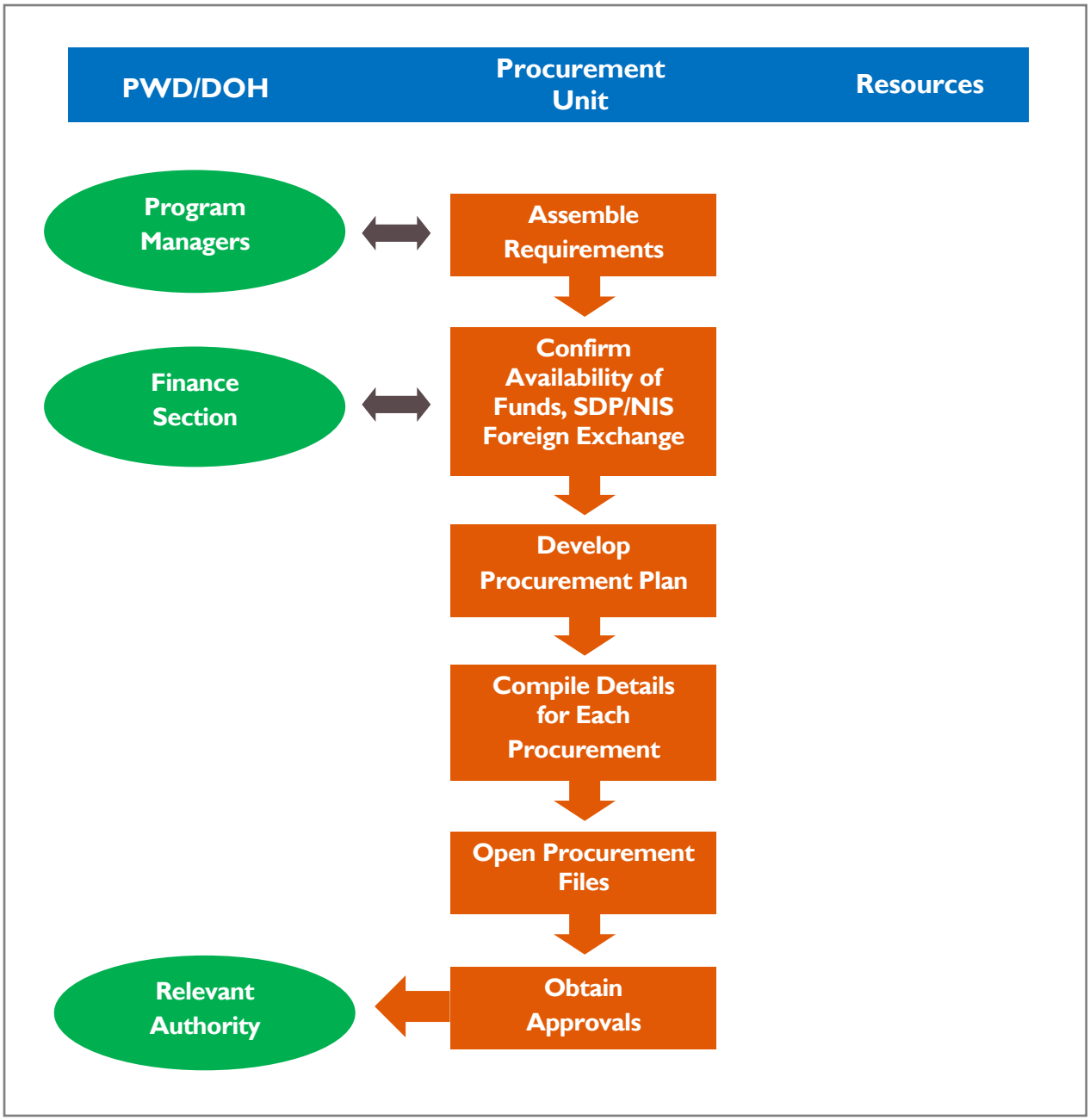
See module 1 for additional information about procurement timelines.

M. Code of Ethics

The Government of Sindh also promotes a business code of ethics for the professional behavior of personnel engaged in procurement and contracting activities. This code is based on the SPPR, 2010–*Amended 2013* Rule 2 Definition Sub-rule(1)(q) Corrupt and Fraudulent Practices.

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

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 11 of SPPR, 2010–Amended 2013* states—

> *Mandatory Provision of Procurement Plan - All procuring agencies shall devise a mechanism for planning in detail for all proposed procurements, determining the requirement of the procuring agency, within its available resources, and prepare an annual or a longer term rolling plan, detailing the procurement methods applicable for specific procurements.*

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 Sindh 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 sectionin 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 9 of SPPR, 2010–Amended 2013*. 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 9 of SPPR, 2010–Amended 2013 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 Sindh, 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 *Rule13 of SPPR, 2010–Amended 2013*.

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

6. Obtain Approvals

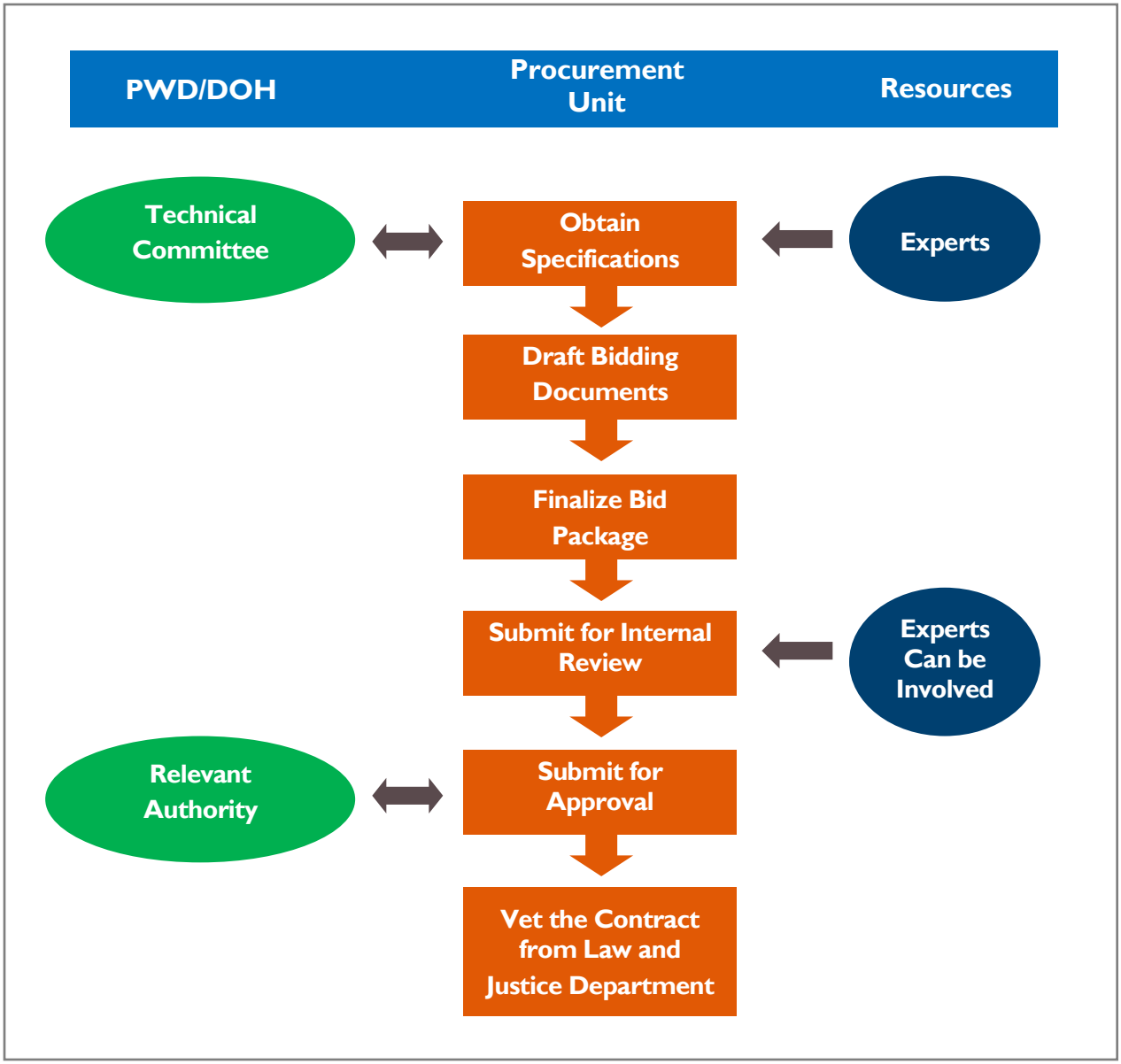
Under *Rule14 of SPPR, 2010–Amended 2013,* approval by the relevant authority of the procurement plan constitutes administrative and financial approval for—

- 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 Rule 43(1) of SPPR, 2010–Amended 2013: "No bidder shall be allowed to alter or modify his bid after the expiry of deadline for the receipt of the bids. Provided that the procuring agency may ask the bidders for clarifications needed to evaluate the bids but shall not permit any bidder to change the substance or price of the bid."

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 3 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 3 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 3 for a sample BDS.

4. Ineligible Bidders

Lists of firms that are excluded from bidding on specific contracts under *Rule 35 of SPPR, 2010–Amended 2013* are on the Sindh 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 3 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 3 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 13 of SPPR, 2010–Amended 2013*. 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 technicalspecifications for contraceptives in appendix3.

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 3for a sample schedule of requirements form.

9. Evaluation and Qualification Criteria

Rule 21 (a) of SPPR, 2010–Amended 2013states that "the procuring agencies shall formulate an appropriate evaluation criteria, listing all the relevant information against which a bid is to be evaluated and criteria of such evaluation shall form an integral part of the bidding documents. The failure to provide a clear and unambiguous evaluation criteria in the bidding documents shall amount to mis-procurement."

The purchasing unit (PU) announces the criteria in the SBD (*Rules 29 and 30 of SPPR, 2010–Amended 2013*) 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

1. **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 3for a sample bid submission form.

2. **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 governmentpolicy—separates foreign and domestic bidders.

See appendix 3for sample price schedule forms for contraceptives manufactured inside and outside Pakistan.

3. **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 3for a sample of the manufacturer's authorization letter.

4. **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 3for sample bid security forms.

5. **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 3 for a sample contract agreement form.

6. **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 3for a sample performance security form.

7. **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 3 for a sample bank guarantee for advance payment form.

8. **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 3 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 documentthat 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.

2.1If the specifications offered are inappropriate, based on the information above and the examples in appendix 3, 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 documentcomponents.

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 3—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 BDS

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 *SPPR, 2010–Amended 2013*.

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 29 of SPPR, 2010–Amended 2013*, 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 SPPR Authority, in accordance with *Rule 35 of SPPR, 2010–Amended 2013*. 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.

5.3Givebidders 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

SBSs 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 *specificcriteria* 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 Additional 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. BDS 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 the 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; SPPR, 2010–*Amended 2013*; 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:
Confirmthat the L/C capability has been arrangedwith a registeredbank 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 procuringentitycannotsign the contractuntil the pharmaceutical contraceptives are registered in Pakistan. It iscritically important for the procurement unit to know the registration status and to monitor progress, because the drugregulatoryprocedurescandelaycontractsigning 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, negotiableB/L to aspecificbank for payment, the contract clause about shipping documents should not require the seller to sendit—the original, negotiableB/L—to the purchaserwithotheradvance shipping documents. (The purchaserreceives the B/Lfrom the commercial bankafter the supplierispaid. Seeinformation 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 IFB

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 21 of SPPR, 2010–Amended 2013*. 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.

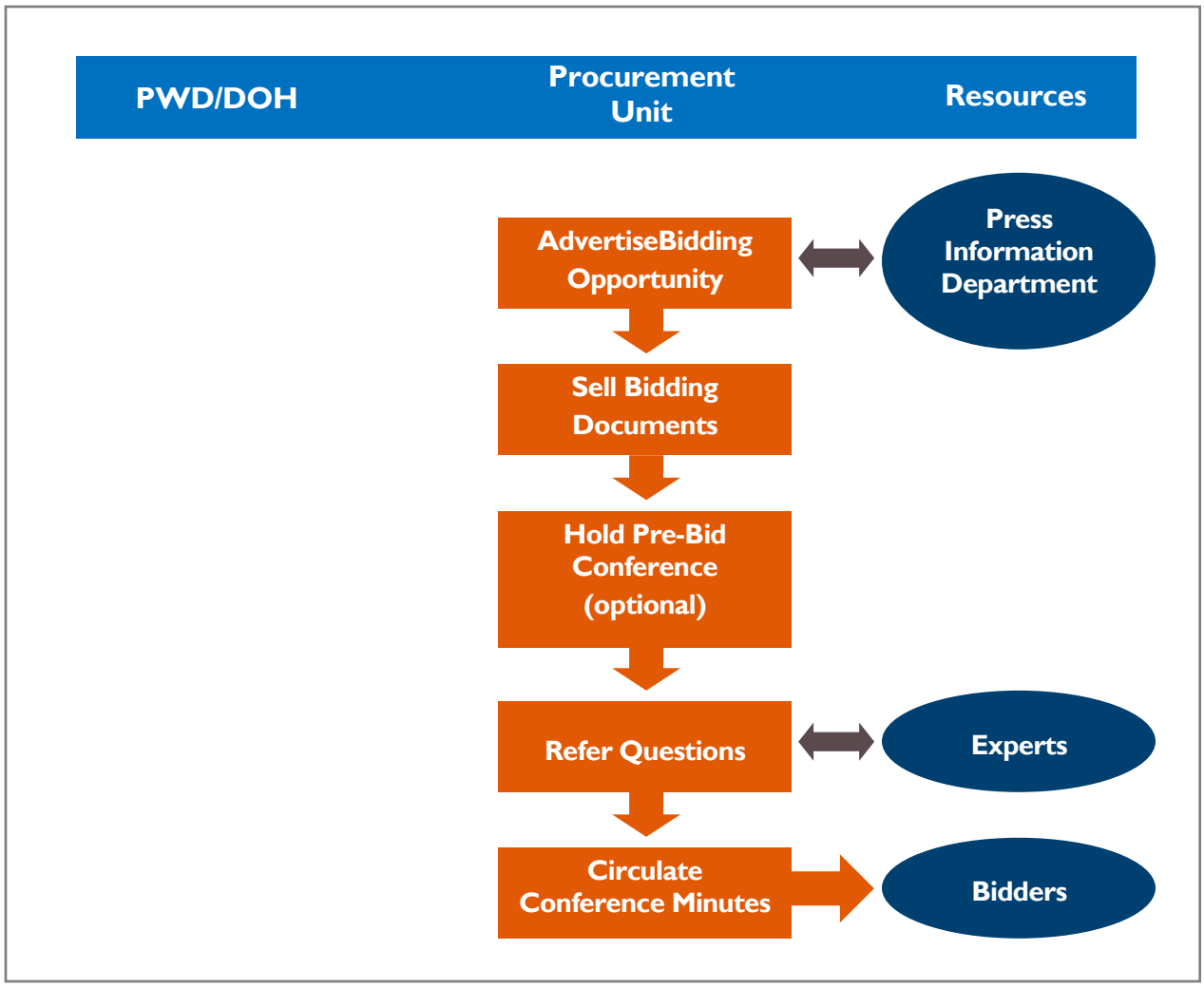
20. Submit Draft Bidding Documents for Internal Review

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. Advertisethe 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 1 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*Rule17(1) of SPPR, 2010–Amended 2013*.

All procurement opportunities over 1 million rupees shall be advertised on the authority's website, as well as in the newspapers as prescribed under *Rule 17 (1)(a) of SPPR, 2010–Amended 2013*.

For international competitive bidding, *Rule 17 (6) of SPPR, 2010–Amended 2013* requires that the procurement opportunity be published in print media or newspapers with a wide circulation, as well as on the SPPRA website, concerned departments, and any international advertisement sources. Print media advertisements should be placed in at least three widely circulated leading dailies in English, Urdu, and Sindh 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, dgMarket. 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 45 days for ICB *(Rule18 of SPPR, 2010–Amended 2013)*.

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.

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

2.3Prepare 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—*Rule 21 (a) of SPPR, 2010–Amended 2013*. 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—*Rule 24 (2) of SPPR, 2010–Amended 2013*.

2.5Set 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 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. 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 whopurchasebidding documents must receiveexactly the sameinformation.

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.

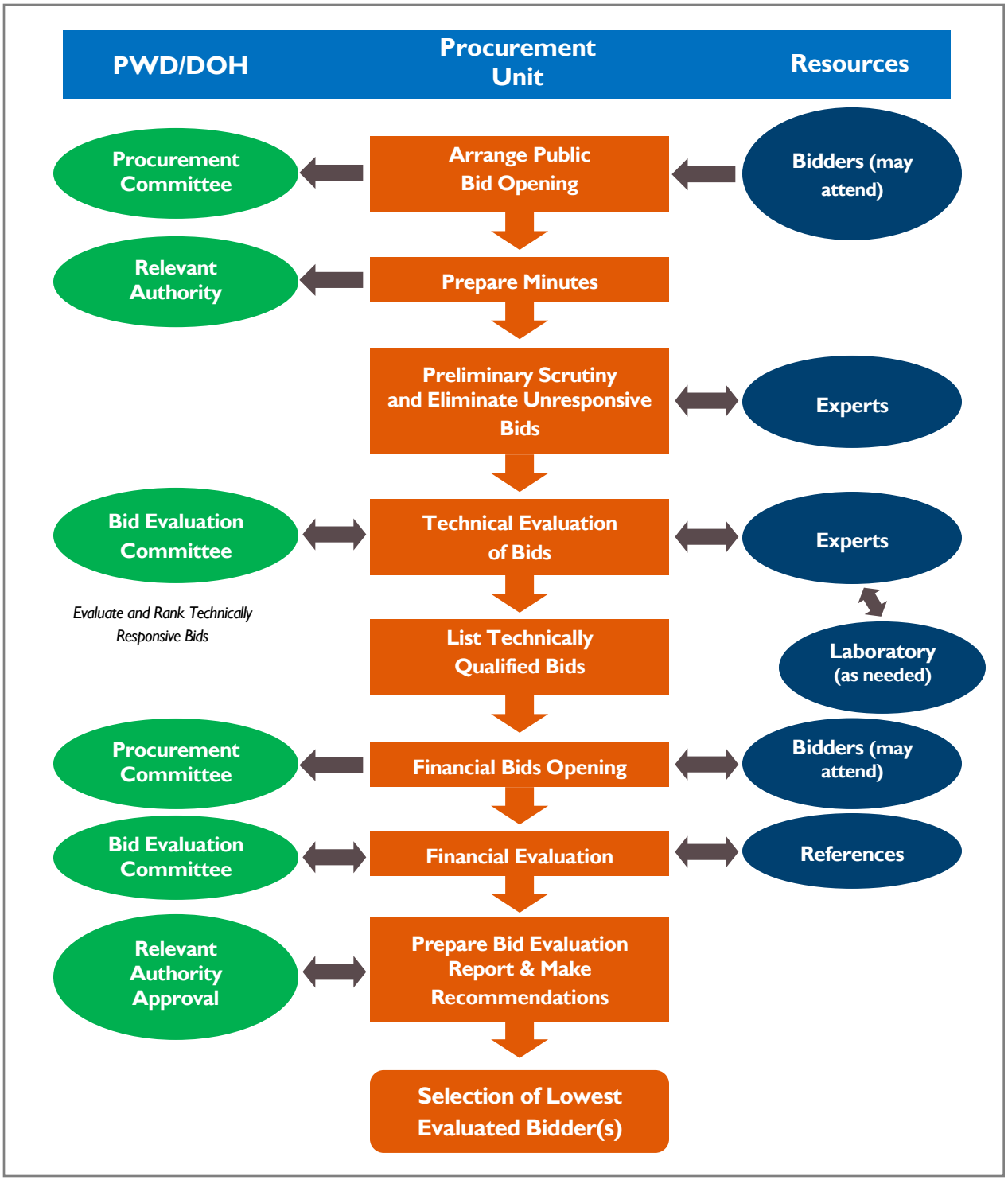
6. Receiving and Managing Bids

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: Bid Opening, Evaluation, and Selection

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 46 (2) of the SPPR, 2010–Amended 2013*. The rule states—

> *(2) single-stage two-envelope bidding procedure shall be used for goods and services where the bids are to be evaluated on technical and financial grounds and price is taken into account after technical evaluation*

The evaluation and selection of a winning bidder is governed by the *Rule 42 of SPPR, 2010–Amended 2013*, which states—

> *(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.*

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 *Rule 41 of the SPPR, 2010–Amended 2013*.

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 bidopening and report, have no further contact withbiddersuntil the winner isidentified and notified. No meetings or conversations canbeheldbetween the purchaser and biddersduring the evaluationprocess.

C. Bid Evaluation Format

SPPR, 2010–Amended 2013 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 *Rule 42 of SPPR, 2010–Amended 2013*; 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 46 (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:

Testingissometimesrestricted to samplesfromseveral prospective supplierswiththe lowestsubstantially responsive bids; but, itcanalsobereserved for bidsfromnew or previouslyunreliablesuppliers. In this case, testingwouldbedelayeduntilthe financialevaluationiscomplete.

Testingsamplessubmittedwithbids are not appropriate for healthsectorgoods—contraceptives, pharmaceuticals, and vaccines—becausethiswill not ensurethe quality of *a product batch to beproduced 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 SPPRA 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 steprequiressignificantjudgment and extreme care. The procuringentitymay regard a bid as responsive, even if it has minordeviations.

Bidsthat are determined to be*not substantially responsive*cannotbeconsideredfurther; theywill not beevaluated on the basis of price. Major deviationsfrom the commercial requirements (step 7 above) and technicalspecifications(step 8 above) are a basis for rejectingbids. Bidders are *not*allowed to correct or withdrawmaterialdeviations or reservationsafterbids have been opened.

Definitions:
A bidisconsidered*substantially responsive*whenitispresented in the requiredmanner and appears to include all required information, samples, statements, securities, signatures, forms, and supporting documentation; and has no materialdeviationsfrom or reservations to the terms, conditions, and specificationsin the bidding documents.

A *materialdeviation*is a significant and unacceptabledifferencefrom the requirementsstated in the bidding documents. As a generalrule, major—or material—deviations are thosethat, if accepted, would not fulfill the purposes for which the bidisrequested, or wouldprevent a faircomparisonwithbidsthat are properlycompliantwith 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 anyrights 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 and cannot receive 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 considers corrections, discounts, and other factors, and gives them a value. Bidding documents must list factors to be considered, in addition to price, and must describe how 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 footnotesunusual 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 48 of SPPR, 2010–Amended 2013).*

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 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.

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 responsiblefor promptly approving the award recommendation.

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

- Increase the confidence of bidders in the procurement process, which encourages bidders to compete for Government of Sindh contracts; thereby, increasing competition that can lead to reduced product prices.
- 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 2(1)(aa) of SPPR, 2010–Amended 2013*.
- 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—

- ask for any clarification required from the bid evaluation committee
- reject the recommendation, clearly documenting in writing the reasons for the rejection, and request a re-evaluation
- reject the recommendations, clearly documenting, in writing, the reasons for the rejection; and issue instructions to reprocess the procurement, in accordance with the *SPPR, 2010–Amended 2013*.

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.

6. For all contract awards, the purchaser must complete Contract Award Performa I (see annexure 50) and Contract Award Performa II (see annexure 51) for posting on the SPPRA website, under *Rule 50 of SPPR, 2010–Amended 2013*.

L. Announcement of Evaluation Reports

Under *Rule 45 of SPPR, 2010–Amended 2013*, 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 38 of SPPR, 2010–Amended 2013),* 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.

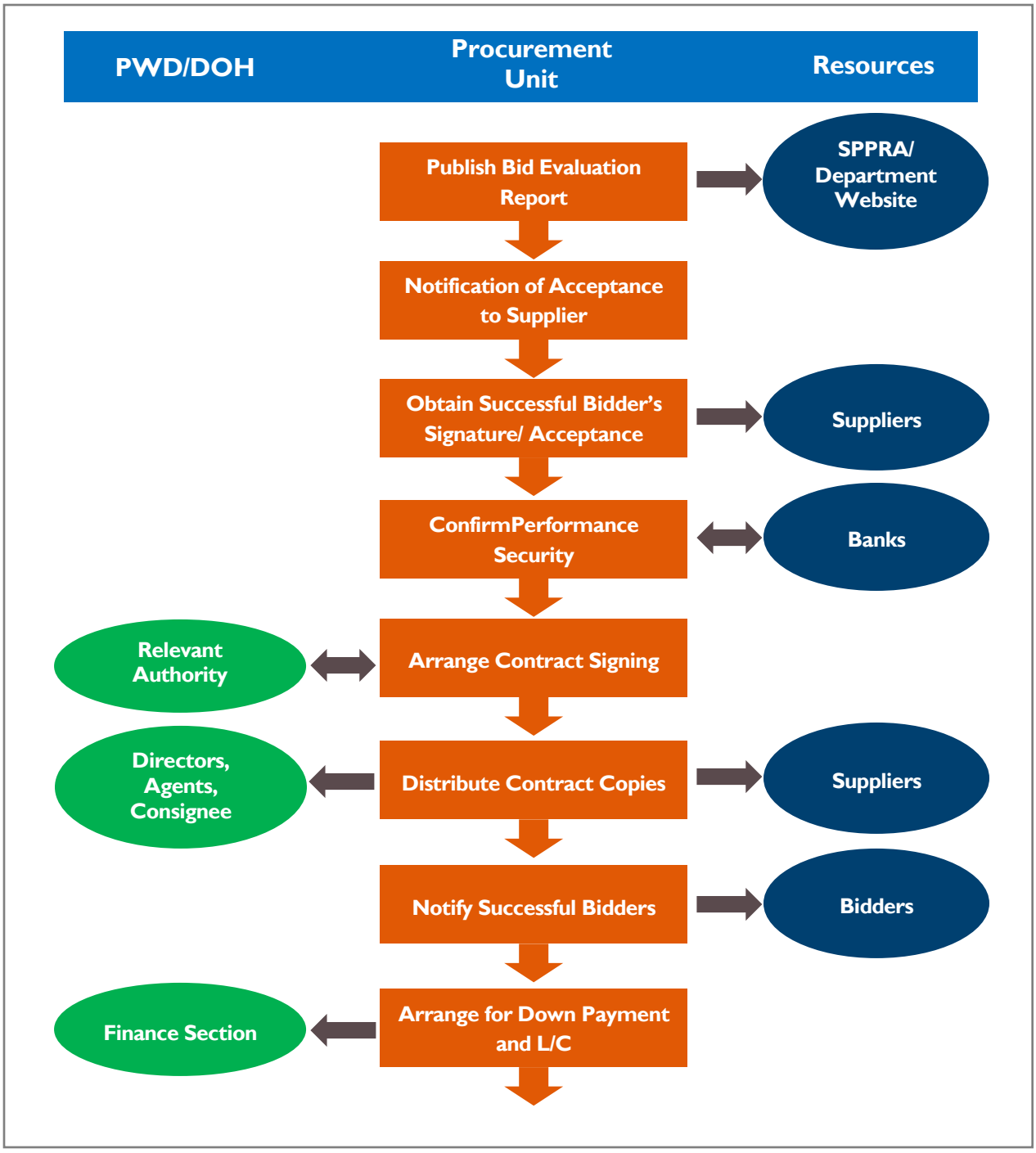
N. N. Redressal of Grievances

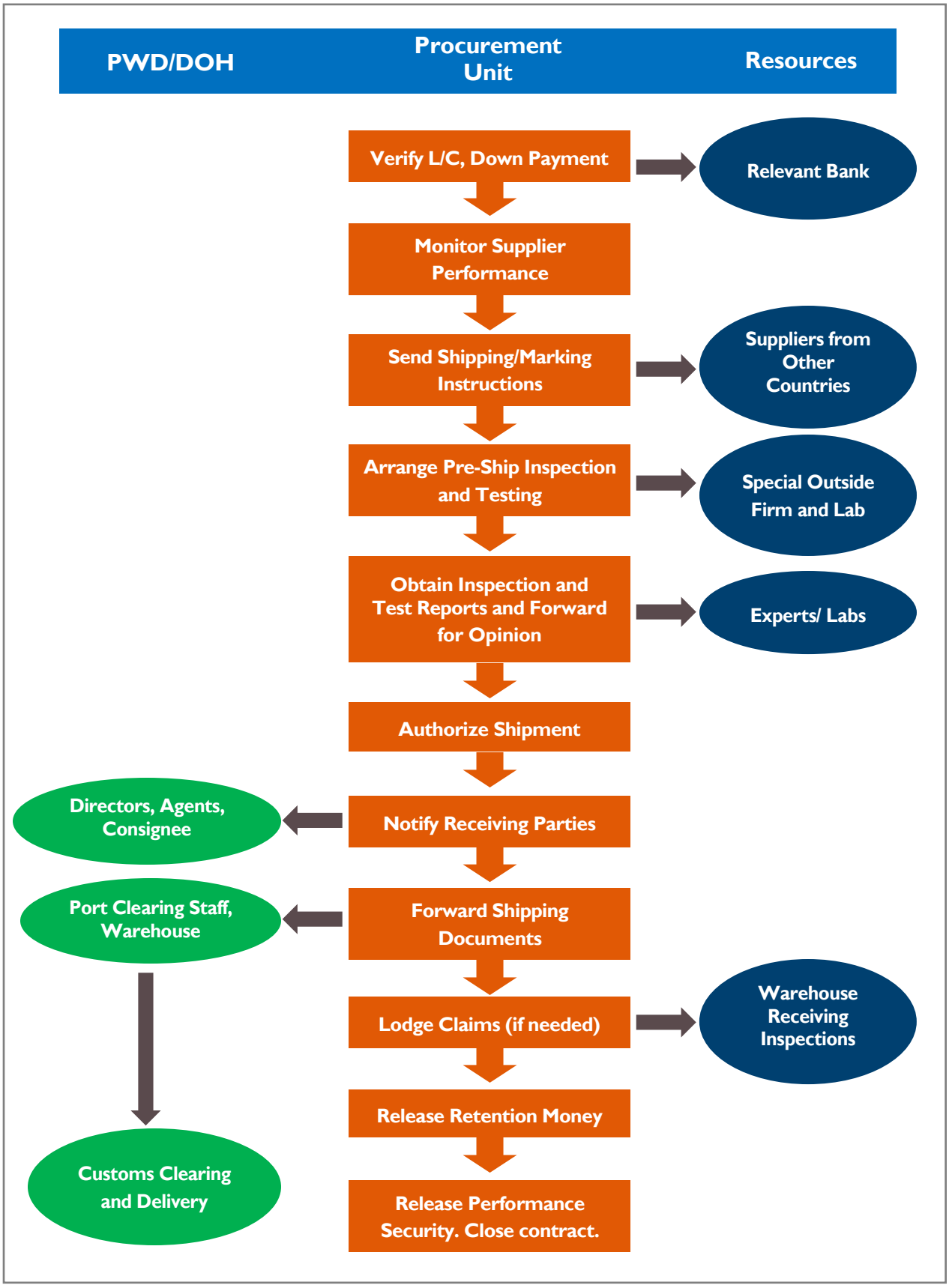
If any bidder thinks they did not receive fair and impartial treatment after submitting their bid, they can file a written complaint in accordance with *Rule 31 of SPPR, 2010 Amended 2013*, after the issuance of notice inviting the tender.

The grievance committee, comprising an odd number of people, shall review the grievance andmake 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 grievance committee fails to resolve the complaint, the procuring unit shall not award the contract—*Rule 31(7) of SPPR, 2010–Amended 2013*.

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 the procedure given in *Rule 32 of SPPR, 2010–Amended 2013*.

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 Sindh, under *Rule 50*, requires the procuring entity to publish award information on their public websites within seven days of the award of contract. *Rule 50 of SPPR, 2010–Amended 2013* states—

> *Within seven days of the award of contract, procuring agency shall publish on the website of the Authority and on its own website, if such a website exists, the results of the bidding process, identifying the bid through procurement identifying number, if any, and the following information:*
>
> *(1) Evaluation Report;*
>
> *(2) Form of Contract and Letter of Award;*
>
> *(3) Bill of Quantities or Schedule of Requirement.*

B. Notification of Acceptance

Rule 49 of SPPR, 2010–Amended 2013 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 SPPRA 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—

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 seven days after the bid evaluation report has been published (*Rule 45 of SPPR, 2010–Amended 2013*) 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

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

[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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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.

2.1 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 procuringagencycannotsign the contractuntil the registration for contraceptives—oral pills, injections, implants, etc., requiredunder the Drug Act of 1976, are complete. It iscritically important for the procurement unit to know the registration statusand to monitor progress, becausedrugsregulatoryprocedurescandelaycontractsigning and, therefore, 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 SPPR, 2010–Amended 2013* and return bid securities to the unsuccessful bidders under *Rule 37 of SPPR, 2010–Amended 2013*.Do not take this stepuntil 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 10 million rupees for goods and works, and 2.5 million rupees for services.

D. Payment Arrangements

For local procurements, follow the payment procedure given in the bidding documents and under *Rule 54 of SPPR, 2010–Amended 2013*.

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.

1. Arrange Down Payment

If a down payment is required, an official of the procuring agencymust 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, theprocurement unitshould—

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.

2.3Develop 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.

2.4Obtain 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.

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

3. Verify Down Payment and/or Letter of Credit

Theprocurement officeshould 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. 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 7.

Theprocurement 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. 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. 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 *Rule 57 of SPPR, 2010–Amended 2013* which states:

(1) Except for defect liability or maintenance by the supplier, consultant or contractor, as specified in the conditions of contract, performance of the contract shall be deemed close on the issue of overall delivery certificate, certificate of completion of deliverables, 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 supplier or contractor to submit final bill and the procuring agency to carry out any inspection of goods, works or services related thereto, as provided in the contract agreement and auditors to do substantial audit.

(2) In case of defect liability or maintenance periods, defect liability certificate shall be issued within thirty days of the expiry of the said period enabling the supplier or contractor to submit the final bill.

(3) Except for unsettled claims, which shall be resolved through arbitration, and shall be paid within the time given in the conditions of contract.

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 (*Rule 9 of SPPR, 2010–Amended 2013).*

Annexures

Annexure 1:Incoterms

Annexure 1:International Commercial Terms

The rules or 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 to interpret the most commonly used terms in international trade. They are intended to reduce or remove altogether uncertainties that might arise from different interpretation of the rules in different countries.

Incoterms 2010

The eighth published set of pre-defined terms, *Incoterms 2010,* defines 11 rules. *Incoterms 2000* had 13 terms, but four terms—Delivered At Frontier (DAF); Delivered Ex Ship (DES); Delivered Ex Quay (DEQ); and Delivered Duty Unpaid (DDU)—were eliminated. Two new terms were introduced—Delivered At Terminal (DAT) and Delivered At Place (DAP).

Note:
Carrier meansanypersonwho, in a contract of carriage, undertakes to perform or to procure the performance of carriage by rail, road, sea, air, inlandwaterway, or a combination of these modes. If the buyerinstructs the seller to deliverthe cargo to a person—e.g., a freightforwarderwhois not a *carrier*—the seller isconsidered to have fulfilledhis obligation to deliver the goods as soon as the goods are in the custody of thatperson.

Transport terminalmeansarailway terminal, a freight station, a container terminal or yard, a multi-purpose cargo terminal, or anysimilarreceiving point.

Containerincludesanyequipmentused to hold cargo; e.g., all types of containers and/or flats, whether ISO are accepted or not, trailers swap bodies, Roll on/Roll off equipment, or igloos; the termapplies to all modes of transport.

Departure Term

1.Ex Works (EXW) (named place of delivery)

The seller fulfills his obligation to deliver when he has made the goods available at his premises (i.e., works, factory, warehouse, etc.) to the buyer. In particular, he 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 in taking the goods from the seller's premises to the desired destination. This term thus represents the minimum obligation for the seller.

EXW should not be used when the buyer cannot carry out export formalities directly or indirectly. In these circumstances, use the FCA term.

Shipment Terms—Main Carriage Paid by Buyer

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

The seller fulfills his obligation to deliver when is indicated by the buyer, the seller can choose, within the place or range stipulated, where the carrier shall take the goods into his charge. 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 must bear all costs and risks of loss of or damage to the goods. The FAS term requires the seller to clear the goods for export and the buyer to complete 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 been passed over the ship's rail, at the named port of shipment. From that moment on, the buyer must 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 serves no practical purpose, such as in the case of roll-on/roll-off or container traffic, use the FCA term.

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 the cost up to the destination point; risks are transferred to the buyer at the point of shipment.

5.CFR (named port of destination)

The seller must pay the costs and freight necessary to deliver the goods to the named port of destination. However, the risk of loss or damage to the goods, as well as any additional costs from events occurring after the time 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 roll-on/roll-off or container traffic, the Carriage Paid To(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 he must also 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.

*CFR 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 roll-on/roll off or container traffic, use the CIP term.

7. 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 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-to 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 must also 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 may be used for any mode of transport, including multi-modal transport.

Arrival Terms

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

The seller pays for carriage to the terminal, except the costs related to import clearance; the seller also 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 the costs related to import clearance; the seller also assumes all risks before the goods are ready tobe unloaded 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 not unloaded. The seller bears the risks and costs, including duties, taxes, and other charges of delivering the goods thereto, cleared for importation. If the parties want to exclude from the seller's obligations, some of the costs payable on importation of the goods (such as value-added tax [VAT]), should be made clear by adding these words: "Delivered duty paid, VAT unpaid (…named place of destination)."

This term can be used no matter what mode of transport is used.

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 are available and cleared for export at the named point and place at the frontier, but before the customs border of the adjoining country.The term *frontier*can be used for any frontier, including the country of export.Therefore, it is of vital importance 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 are available to the buyer on board the ship, but *not* cleared for import at the named port of destination.The sellermust 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 his obligation to deliver when he has made the goods available to the buyer on the quay (wharf), at the named port of destination, but not cleared for importation.The sellermust bear all risks and costs incurred in bringing the goods to the named port of destination and discharging the goods on the quay (wharf); including duties, taxes, and other charges for delivering the goods.

If the parties wish 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 made clear by adding these words: "Delivered ex quay, VAT unpaid (named port 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 sellermust bear the costs and risks involved in bringing the goods thereto—excluding duties, taxes and other official charges payable upon importation—as well as the costs and risks of carrying out customs formalities.The buyermust pay any additional costs and must bear any risks caused by his failure to clear the goods for import on time.

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

If the parties want 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 any mode of transport.

Incoterms 2010: Responsibilitiesof buyers and sellers

The table below explains the responsibilities of buyers and sellers including the price for each of the Incoterms.

	Load to truck	Export-duty payment	Transport to exporter's port	Unload from truck at the origin's port	Landing charges at origin's port	Transport to importer's port	Landing charges at importer's port	Unload onto trucks from the importer's port	Transport to destination	Insurance	Import Customs Clearance	Import Duties and Taxes
EXW	buyer	buyer	buyer	buyer	buyer	buyer	buyer	buyer	buyer	buyer	buyer	buyer
FCA	seller	seller	seller	buyer	buyer	buyer	buyer	buyer	buyer	buyer	buyer	buyer
FAS	seller	seller	seller	seller	buyer	buyer	buyer	buyer	buyer	buyer	buyer	buyer
FOB	seller	seller	seller	seller	seller	buyer	buyer	buyer	buyer	buyer	buyer	buyer
CFR	seller	seller	seller	seller	seller	seller	buyer	buyer	buyer	buyer	buyer	buyer
CIF	seller	seller	seller	seller	seller	seller	buyer	buyer	buyer	seller	buyer	buyer
CPT	seller	seller	seller	seller	seller	seller	buyer	buyer	buyer	buyer	buyer	buyer
CIP	seller	seller	seller	seller	seller	seller	buyer	buyer	buyer	seller	buyer	buyer
DAT	seller	seller	seller	seller	seller	seller	buyer	buyer	buyer	seller	buyer	buyer
DAP	seller	seller	seller	seller	seller	seller	buyer	buyer	buyer	buyer	buyer	buyer
DDP	seller	seller	seller	seller	seller	seller	seller	seller	seller	buyer	seller	seller

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

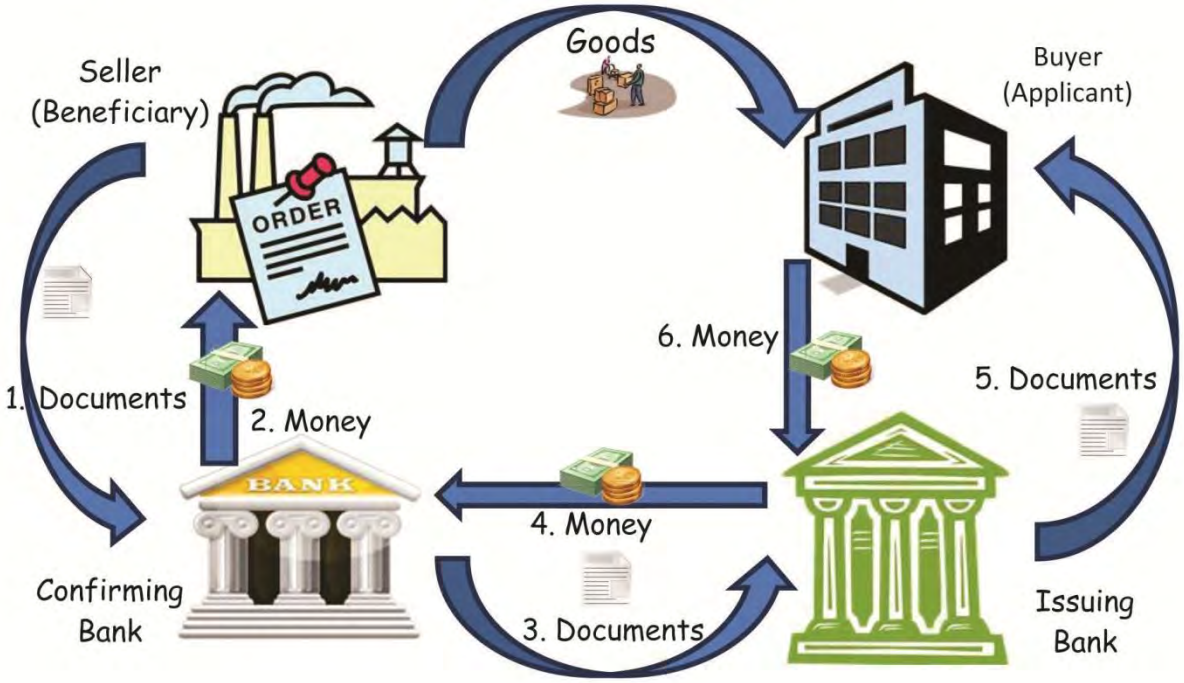
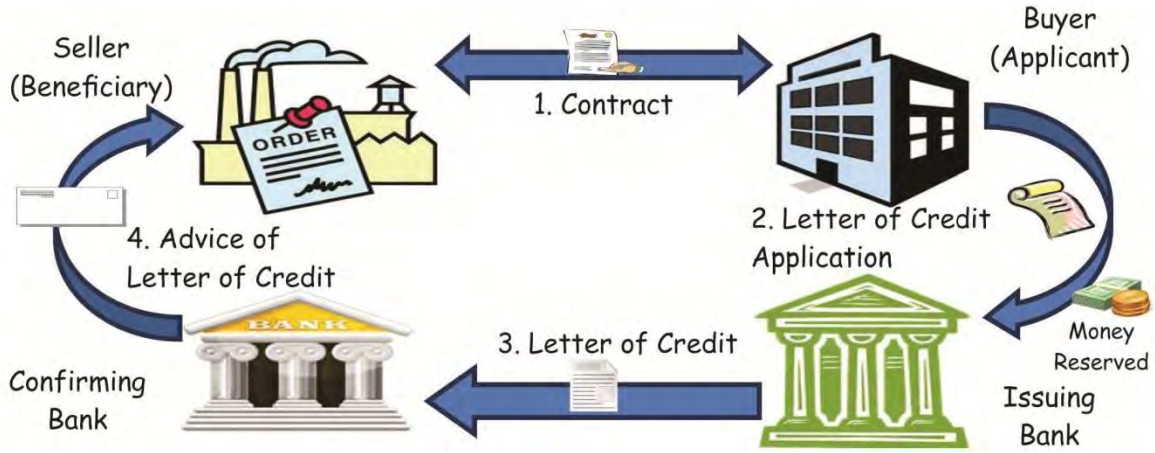


Figure 2: Opening of a Letter of Credit



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) isusually 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 intereston 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 riskfor 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 Sindh Public Procurement Rules 2010–Amended 2013: Rule 2 Definition Sub-Rule (1) (q) Corrupt and Fraudulent Practices. 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 Sindh 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 ofthe laws, rules, and regulations of the Government of Sindh 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 procuringagency 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 / CONSULTANTS

Contract No _____ Dated: _____

Contract Value: _____

Contract Title: _____

(*the/Supplier/Contractor/Consultant*) 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 Sindh (GoS)** or any administrative subdivision or agency thereof or any other entity owned or controlled by it (GoS) through any corrupt business practice.

Without limiting the generality of the foregoing, (*the/Supplier/Contractor/Consultant* 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 Procuring Agency (PA), except that which has been expressly declared pursuant hereto.

(*the/Supplier/Contractor/Consultant*) 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 PA and has not taken any action or will not take any action to circumvent the above declaration, representation or warranty.

(*The/Supplier/Contractor/Consultant* 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 PA under any law, contract or other instrument, be voidable at the option of PA.

Notwithstanding any rights and remedies exercised by PA in this regard, (*the/Supplier/Contractor/Consultant*) agrees to indemnify PA for any loss or damage incurred by it on account of its corrupt business practices and further pay compensation to GoS in an amount equivalent to ten time the sum of any commission, gratification, bribe, finder's fee or kickback given by (*the/Supplier/Contractor/Consultant*) 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 PA.

_____ _____

Procuring Agency **Supplier / Contractor / Consultant**

Annexure 5: Procurement Plan Format

PROCUREMENT PLAN BUDGET:

Department:

Agency:

Procuring Entity Name & Code:

Project / Program Name & Code:

Package No	Description of Procurement Package	Unit	Qty	Procurement Method and Type	Contract Approving Authority	Source of Funds	Est. Cost in Rupees	Time line	Advertise Tender	Tender Opening	Tender Evaluation	Approval To Award	Notification of Award	Signing of Contract	Completion of Contract	Total Time (in days)
1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17
Example	Oral contraceptives, combined estrogen and progestin low-dose; Monthly packet shall contain 28 tablets, 7 tablets shall contain ferrous fumarate	Packet	1.45m	ICB	Ministry	GOP	430m	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 IFB	Limits* (as per *SPPR-2010* of GOS) in PKR	Remarks
Petty purchase	• No bid or quotation only • Invoice from single source	1/- to 24,999/- *Rule 16(d) of SPPR, 2010–Amended 2013*	Should be in accordance with *Rule 4of SPPR, 2010–Amended 2013* (Principles of Procurement)
Request for quotation (RFQ)	Minimum three quotations	25,000/- to 99,999/- *Rule 16(a) of SPPR, 2010–Amended 2013*	Object of procurement should have standard specifications
Direct contracting		*Rule 16(b) of SPPR, 2010–Amended 2013*	For all direct contracting and single-source selection, the rules prescribed by *SPPR, 2010–Amended 2013* apply
National Competitive Bidding (NCB)	Print media (newspapers with wide circulation) and websites of SPPRA and procuring agency	Less than U.S.$10 million in equivalent local currency *Rule 15 (2)b of SPPR, 2010–Amended 2013*	At least three national dailies; English, Sindhi and Urdu (*Rule 17(2) of SPPR, 2010–Amended 2013*
International Competitive Bidding (ICB)	• Print media (newspapers with wide circulation) • Websites of SPPRA and procuring agency • Internationally known website dedicated to particular goods, works, or services • Any widely circulated English language international newspapers	U.S.$10 million or above *Rule 15 (2)a of SPPR, 2010–Amended 2013*	At least three national dailies; English, Sindhi and Urdu (*Rule 17(2) of SPPR, 2010–Amended 2013*

Annexure 7: Estimated Timeline

Estimated Timeline for High-Value Procurement			
Four months or more for budgeting and planning precedes initiation of procurement package			
	In days	In weeks	In months
Initiate procurement	30	4	
Set up file	2		
Gather pertinent information	25		
Summarize data	3		
Develop bid documents	45	6	
Draft ITB, SC, specs, requirements	45		
Solicit receive and open bids	56	8	
Place advertisement and notify	10		
Sell bidding docs	45		
Hold public bid opening	1		
Evaluate bids/obtain approvals	60	9	
Complete standard bid evaluation	60		
Notify award	7	1	
Receive performance security			
Sign contract	21	3	
Open letter of credit	14	2	
Manufacturing lead time	112	16	
Pre-shipment quality check	13	2	
Inspect at supplier's premises	1		
Testing	10		
Authorize shipment	2		
Shipping	40	6	
Delivery	6	1	
Import procedures	5		
Receiving inspection	1		
Acceptance certificate			
Total	**404**	**58**	**13.5**

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 documentof the former Ministries of Health and Population Welfare[3]:"*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.

[3]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.

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.

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 SPPRA 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 percentageof 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)

(inserttitle/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 to supply the following:

(Insert brief summary or list of the required goods)

(Insert brief narrative including background information or further specification, if necessary.) Bidding is open to all suppliers/contractors who can demonstrate (list criteria for eligibility). Interested bidders can inspect the bidding document on the PPRA website (http://pprasindh.gov.pk) or at the address below (insert hours when the documents will be available for inspection). Bidding documents can 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 of all other required documents and samples, where applicable.

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

(Insert full name of procuring agency):	Sector:
Room number:	City or town, postcode, and province:
Building name:	Name and/or title of person to contact:
Street number and name (if appropriate):	Telephone number:

Fax number:

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 Sindh
Population Welfare Department
(Insert address)

To

Technical expert

[3]

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

Bid package No. ___ for (*insert name of goods)*

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

Dear Sir:

Queries raised in the pre-bid conference held on the subject bid package on (*insert date*) are included 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 (*insert 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 Sindh

Population Welfare Department

(Insert address)

To: All bidders

(*insert the names and addresses*)

Subject: Clarification on query raised in pre-bid conference on
Bid Package No. ___ for (*insert name of goods*)
Ref: Pre-bid conference held on (*insert date*)

Dear Sir:

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

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

Thanking you,

Copy for information to:

1. GOS
2. The user office

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

Memo No._____ Date _____

Government of Sindh
Population Welfare Department
(Insert address)

To: M/S

(*All bidders who purchased the bid package*)

Subject: Notification on extension of bid submission date forBid Package No. ___ for (*insert name of goods*)

To facilitate the necessary actions on the reply/clarification to queries raised in the pre-bid conference, held on the subject bid package on (*insert date*), the bidding document selling date and bid submission date are hereby extended as follows:

Event	Previous Date	Extended Date
Bidding document	Up to (*insert date*)	Up to (*insert date*)
Bid submission date	(*insert date)*	(*insert date)*

We will appreciate your earliest response to the above. Please note that the bids aredue for submission on (*insert 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 Sindh

Population Welfare Department

(Insert address)

NOTIFICATION

Bids against Bid Package No. ____ will be opened on (*insert date, time, and venue*). Information about the package is given below.

Bid Package Number	Goods	Quantity	Estimated Cost	Method of Procurement
	(*Insert short description*)	(*Insert quantity with unit*)	(*Insert cost with currency*)	(*Insert 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 the 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:					
PA	**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	BidCurrency	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 formand 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 45 of SPPR 2010–Amended 2013*.
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 Sindh

Population Welfare Department

(Insert address)

Manager, Issuing Bank

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

Subject: Bank Guarantee/Pay Order/Cashier's Check (*insert no. and date*)

You are requested to kindly confirm issuance of the above-named bank guarantee/pay order/cashier's check (*mention no. and date*) submitted to us by (*insert the bidder's name and address*) against bid package no. (*insert no.*).

Information about the instrument is given below.

Type of Guarantee	Issued in Favor of…	Amount and Currency	Validity
(insert whether it is a bank guarantee or pay order or other)	*(insert bidder's name)*	*(insert amount and currency)*	*(insert 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. Does the bid validity period conform to the requirement in the bidding documents? (yes /no)
2. If the bidder is a joint venture, is a joint venture agreement provided? (yes /no /not applicable)
3. If the bidder is not the manufacturer, did the bidder provide a manufacturer's confirmation to warranty obligations? (yes /no /not applicable)
4. If an agent submitted the bid, is the manufacturer's authorization to submit the bid 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. Is this bidder pre-qualified? (yes/no/not applicable)
2. Is this 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 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. Did the bidder ask for price adjustments when a fixed price bid was invited? (yes/no)
2. Did 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 the applicable law, taxes, and duties; and dispute resolution procedures specified 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 *(a)*	Currency(ies) of Bid *(b)*	Corrected Discounted Bid Price(s) *(c)*	Applicable Exchange Rate(s)[1] *(d)*	Evaluation Currency *Bid Price(s) (e)=(c)x(d)*	Evaluation Currency 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 *(a)*	Domestic Preference Group[1] *(b)*	Total Price[2] *(c)*	Exclusions For Preference[3] *(d)*	Revised Total *(e)=(c)-(d)*	Prevailing Tariff (%)[4] *(f)*	Domestic Preference (%)[5] *(g)*	Preference Price[6] *(h)*	Total Comparison Price *(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 (*insertsubject 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

1. Technical evaluation determined the compliance of each responsive bid to the technical specification issued in the bidding documents.
2. {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—

1. record the submitted bid prices
2. correct for any omissions or arithmetic mistakes
3. convert the bid prices to Pakistani rupees, if necessary
4. 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
5. 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 (*insertname of company*) was subjected to qualification examination covering (*add/delete, as applicable*):

1. experience and performance on similar contracts
2. equipment and manufacturing/construction facilities
3. qualifications and experience of personnel
4. financial position
5. local facilities and representation
6. 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)

1. Evaluation report for goods
2. Record of negotiations, if applicable
3. Copies of all bids submitted.

Related documents previously submitted: (Available for reference from the secretariat to the tender committee)

1. 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:	

	(i) 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

3.

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 50: Contract Award Pro Forma I

SINDH Public Procurement Regulatory Authority (SPPRA)

To be completed (filled in) and uploaded on the SPPRA 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:

SPPRA website: _____ Yes/No (federal agencies) (If yes, give date and SPPRA's tender number)

Newspapers: _____ Yes/No (If yes, list names of newspapers and dates)

Tender opened on (*insertdate 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

SINDH Public Procurement Regulatory Authority (SPPRA)

To be completed (filled in) and uploaded to the SPPRA 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 Sindh

Population Welfare Department

(Insert address)

To: M/S *(insert name and address of the bidder)*

Subject: Award notification against bid package no.____ for supplying *(insert short description of goods)*

Dear Sirs,

We are pleased to award you the contract for bid package no. *(insert no.)* for the goods and price as listed below:

Bid Package No. and Short Description of Goods	Total Contract Price with Currency	Basis of Contract
(insert short description of goods)	*(insert price with currency)*	*(insert whether it is a CIF,CFR, or EXW contract or otherwise)*

Please note that the contract will include, among others, the following documents:

1. Form of contract
2. Bid form and the price schedule submitted by the bidder
3. Schedule of requirements (offered by the bidder and accepted by the purchaser)
4. Technical specifications (offered by the bidder and accepted by the purchaser)
5. General conditions of contract
6. Special conditions of contract (filled in)
7. Performance security submitted by the bidder.

Two copies of the contract form are enclosed herewith for you to sign and return to us. Please also submit a performance security in the amount not less than *(insert percentage)* of the contract price,within *(insert 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 ofthird 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)

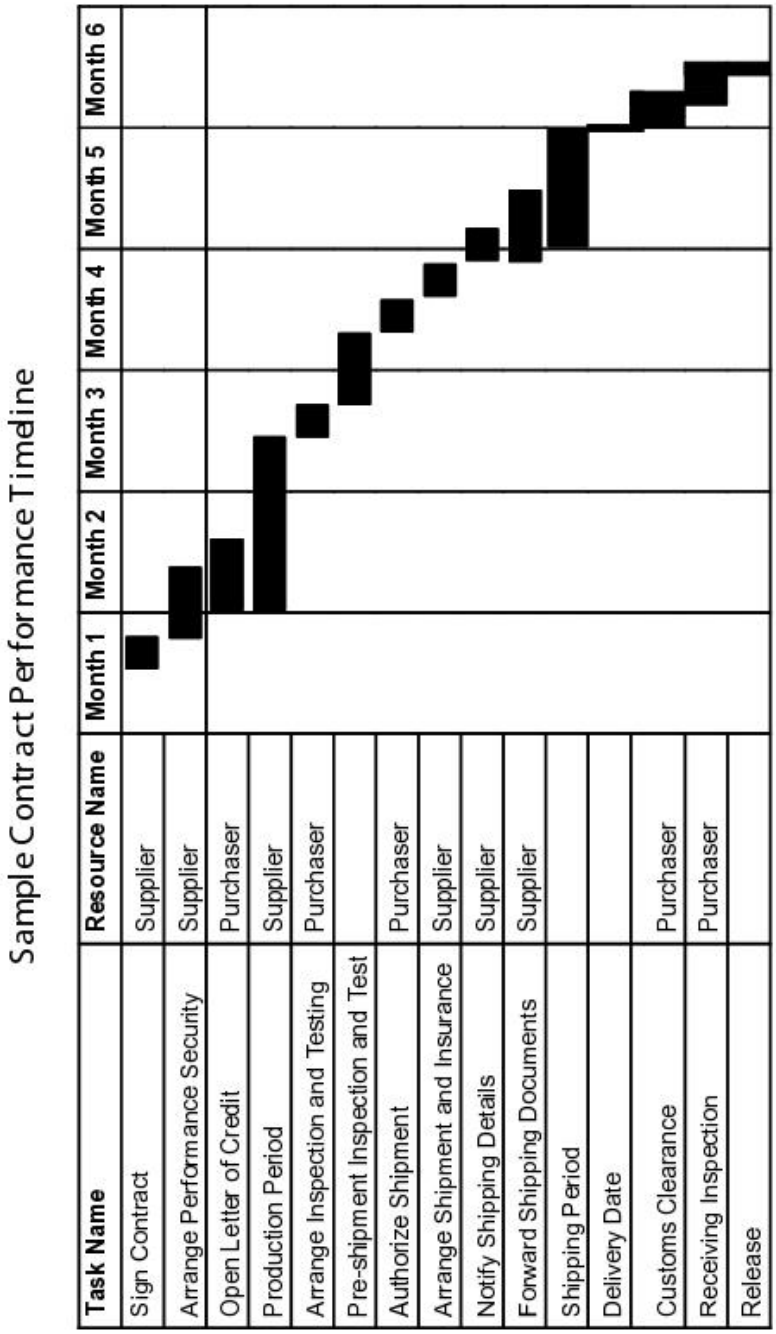
Supplier

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



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 Sindh)

Prior to Shipment of Commodities

1. Contact _____(insert name and address of contracted inspection agent/company)

Upon Receipt of Authorization for Shipment

2. 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 strappingto secure the load tightly and firmly, without an overhang. Plastic shrink wrap can be used to stabilize and protect palletized loads.
3. Arrange for a sufficient number of standard 20-foot containers to accommodate the shipment.Goods may not be consolidated with other freight.
4. 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.
5. 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.
6. Shipinstandard 20-footcontainersviaoceanfreighton the flagvesselof _____(*insert country*), to _____(*insert name and address of consignee including city and country*)
7. Commodities must be insured for 110 percent of their total CIF value, covering all risks from warehouse to port of unloading.
8. Do not ship freight *collect*. Freight must always be *prepaid*.
9. 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.

10. 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*)

11. The bill of lading must include container number(s), contract number, letter of credit number, and country of origin, in addition to standardbill of lading information requirements.
12. 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 theL/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.

13. 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 Sindh

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: _____ (*insert supplier's name*)

Ref: Contract number: _____

Letter of credit number:_____

Authorization for Shipment:

Re: _____ (*insert description of goods*)

Pre-shipment inspection and test data have been received and approved by:

_____ (*insert purchaser's name*)

Signature:

Signature of this document by the authorized representative indicates that the commodity conforms to the contract number_____ and it 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: Sindh Public Procurement Rules 2010 Amended 2013

GOVERNMENT OF SINDH
SERVICES, GENERAL, ADMINISTRATION AND
COORDINATION DEPARTMENT
(REGULATION WING)
Amended 8th October 2013

N O T I F I C A T I O N

NO. SORI(SGA&CD):2-30/2010: In exercise of the powers conferred by Section 26 of the Sindh Public Procurement Act, 2009, the Government of Sindh are pleased to make the following rules and amendments in the Sindh Public Procurement Rules 2010:

1. **Short title and commencement**
   1) These rules shall be called the Sindh Public Procurement Rules, 2010 Amended 2013.
   2) They shall come into force at once.
   3) They shall be applicable throughout the province.

Part I - GENERAL PROVISIONS

2. **Definitions**

(1) In these rules, unless there is anything repugnant in the subject or context;

(a) "Act" means Sindh Public Procurement Act, 2009;

(b) "Authority" means the Sindh Public Procurement Regulatory Authority established under Section 3 of Sindh Public Procurement Act, 2009;

(c) "Best Evaluated Bid" means in case of Public Private Partnership projects, a bid, which attains the highest score under criteria laid down in Rule 84, read with respective bidding documents;

(d) "Bid" means a tender, or an offer by a person, consultant, firm, company or an organization expressing willingness to undertake a specified task at a price, in response to an invitation by a Procuring Agency;

(e) [XXX][1]

(f) [XXX][2]

(g) ["Bidding Documents" means the documents notified by the Authority for preparation of bids in uniform manner;][3]

(h) "Bidding Process" means the procurement procedure under which sealed bids are invited, received, opened, examined and evaluated for the purpose of awarding a contract;

(i) "Blacklisting" means barring a bidder, contractor, consultant or supplier from participating in any future procurement proceedings by the procuring agency;

(j) "Calendar Days" means days including all holidays;

(k) "Competent Authority" means an officer of the Procuring Agency empowered to exercise financial powers and approve the award of contract for procurement of goods, works or services, as the case may be;

(l) "Conflict of Interest" means -

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;

(m) "Consultant" means a professional who can study, design, organize, evaluate and manage projects or assess, evaluate and provide specialist advice or give technical assistance for making or drafting policies, institutional reforms and includes private entities, consulting firms, legal advisors, engineering firms, construction managers, management firms, procurement agents, inspection agents, auditors, international and multinational organizations, investment and merchant banks, universities, research institutions, government agencies, nongovernmental organizations, and individuals;

(n) "Consulting Services" means services of an advisory and intellectual nature provided by consultants using their professional skills to study, design, organize, and manage projects, encompassing multiple activities and disciplines, including the crafting of sector policies and institutional reforms, specialist advice, legal advice and integrated solutions, change management and financial advisory services, planning and engineering studies, and architectural design services, supervision, social and environmental assessments, technical assistance, and programme implementation;

(o) "Contract" means an agreement enforceable by law and includes general and special conditions, specifications, drawings and bill of quantities;

(p) "Contractor" means a person, firm, company or organization that undertakes to execute works including services related thereto, other than consulting services, incidental to or required for the contract being undertaken for the works;

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[1] Omitted vide SGA&CD Notification No. SORI(SGA&CD)2-30/2010 dated 8th October, 2013

[2] Omitted vide SGA&CD Notification No. SORI(SGA&CD)2-30/2010 dated 8th October, 2013

[3] Amended vide SGA&CD Notification No. SORI(SGA&CD)2-30/2010 dated 8th October, 2013

(q) "Corrupt and Fraudulent Practices" means either one or any combination of the practices given below;

i. **"Coercive Practice"** means any impairing or harming, or threatening to impair or harm, directly or indirectly, any party or the property of the party to influence the actions of a party to achieve a wrongful gain or to cause a wrongful loss to another party;

ii. **"Collusive Practice"** means any arrangement between two or more parties to the procurement process or contract execution, designed to achieve with or without the knowledge of the procuring agency to establish prices at artificial, noncompetitive levels for any wrongful gain;

iii. **"Corrupt Practice"** means the offering, giving, receiving or soliciting, directly or indirectly, of anything of value to influence the acts of another party for wrongful gain;

iv. **"Fraudulent Practice"** means 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;

v. **"Obstructive Practice"** means harming or threatening to harm, directly or indirectly, persons or their property to influence their participation in a procurement process, or affect the execution of a contract or deliberately destroying, falsifying, altering or concealing of evidence material to the investigation or making false statements before investigators in order to materially impede an investigation into allegations of a corrupt, fraudulent, coercive or collusive practice; 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, or acts intended to materially impede the exercise of inspection and audit rights provided for under the Rules.

(r) "Emergency" means 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 person(s), property or the environment;

(s) [XXX][4]

(t) "Government" means the Government of Sindh;

(u) "Head of the Department" means the administrative head of the department or the organization;

(v) ["Lowest Evaluated Bid" means a bid most closely conforming to evaluation criteria and other conditions specified in the bidding document, having lowest evaluated cost;][5]

(w) "Lowest Submitted Price" means the lowest price quoted in a bid, which is otherwise not substantially responsive;

(x) [XXX][6]

(y) "National Company or Firm" means any enterprise, firm or company set up or incorporated in Pakistan;

(z) "Notice Inviting Tender" means the notice issued by a Procuring Agency through publication in the newspapers or through electronic means for the purpose of inviting bids, or applications for pre-qualifications, or expression of interests, which may include Tender Notice, Invitation for Bids, Notice for Pre-qualifications or Request for Expression of Interests;

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[4] Omitted vide SGA&CD Notification No. SORI(SGA&CD)2-30/2010 dated 8th October, 2013
[5] Omitted vide SGA&CD Notification No. SORI(SGA&CD)2-30/2010 dated 8th October, 2013
[6] Omitted vide SGA&CD Notification No. SORI(SGA&CD)2-30/2010 dated 8th October, 2013

(aa) **"Open Competitive Bidding"** means a fair and transparent specified procedure defined under these Rules, advertised in the prescribed manner, leading to the award of a contract whereby all interested persons, firms, companies or organizations may bid for the contract and includes both National and International Competitive Biddings;

(bb) **[XXX][7]**

(cc) **[XXX][8]**

(dd) **"Public Private Partnership"** means a contractual arrangement between the public and private sectors, built on the expertise and resources of each partner that best meets clearly defined public needs through appropriate allocation of resources, risks and rewards;

(ee) **"Public Private Partnership Unit Sindh" or "Unit"** means the entity established within the Finance Department, Government of Sindh under the Public Private Partnership institutional framework;

[(eee) "Response time" means, the period starting from the first date of issuance of bidding documents up to last date of issuance of bidding documents.]**[9]**

(ff) [XXX][10]

(gg) "Services" means any object of procurement other than goods or works, and includes consultancy services;

(hh) **[XXX][11]**

(ii) "Supplier" means a person, firm, company or an organization that undertakes to supply goods and services related thereto, other than consulting services, required for the contract;

(jj) "Value of Money" means best returns for each rupee spent in terms of quality, timelines, reliability, after sales service, upgrade ability, price, source, and the combination of whole-life cost and quality to meet the procuring agency's requirements.

(kk) **[XXX][12]**

(2) The expressions used but not defined in these rules shall have the same meanings as are assigned to them in the Act and, if not defined there, as in the ordinary usage of language.

3. **Scope and Applicability –** Save as otherwise provided, these rules shall apply to all procurements for goods, works, services including consultancy services and public private partnership projects, carried out by all procuring agencies.
4. **Principles of Procurements –** While procuring goods, works or services, procuring agencies shall ensure that procurements are conducted in a fair and transparent manner and the object of procurement brings value for money to the agency and the procurement process is efficient and economical.
5. **Conflict with International and Inter-Governmental Agreements –** In the event that these rules are inconsistent with, or in conflict with, any obligation or commitment of Government arising out of an international treaty or an agreement with a foreign country or countries, or any international financial institution, the provisions of such international treaty or agreement

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[7] Omitted vide SGA&CD Notification No. SORI(SGA&CD)2-30/2010 dated 8th October, 2013
[8] Omitted vide SGA&CD Notification No. SORI(SGA&CD)2-30/2010 dated 8th October, 2013
[9] Inserted vide SGA&CD Notification No. SORI(SGA&CD)2-30/2010 dated 8th October, 2013
[10] Omitted vide SGA&CD Notification No. SORI(SGA&CD)2-30/2010 dated 8th October, 2013
[11] Omitted vide SGA&CD Notification No. SORI(SGA&CD)2-30/2010 dated 8th October, 2013
[12] Omitted vide SGA&CD Notification No. SORI(SGA&CD)2-30/2010 dated 8th October, 2013

shall override the provisions of these Rules to the extent of that inconsistency or conflict as the case may be.

6. **Language**

(1) All communications and documentation related to procurements of Government shall be in English, Urdu or Sindhi:

Provided that notice inviting tenders, notices for pre-qualifications and request for expressions of interest shall be issued in aforementioned three languages.

(2) In case of any dispute reference shall be made to the original documentation retained on record and decision shall be made in accordance with such original documentation.

7. **Constitution of a Procurement Committee –** The procuring agency shall, with approval of its Head of the Department, constitute as many procuring committees, as it deems fit, each comprising odd number of persons and headed by a gazetted officer not below the rank of BS-18, or if not available, the officer of the highest grade, and shall ensure that at least one third of the members of a procurement committee are from the agencies or departments other than the procuring agency.

8. **Functions and Responsibilities of Procurement Committee(s) –** Procurement committee(s) shall be responsible for;

1) Preparing bidding documents;
2) Carrying out technical as well as financial evaluation of the bids;
3) Preparing evaluation report as provided in Rule 45;
4) Making recommendations for the award of contract to the competent authority; and
5) Perform any other function ancillary and incidental to the above.

MAINTENANCE OF RECORD

9. **Record of Procurement Proceedings**

(1) All procuring agencies shall maintain a record of their respective procurement proceedings along with all associated documentation for a minimum period of five years;

(2) Such maintenance of record shall be subject to the regulations framed in this regard from time to time.

10. **Transparency –** The procuring agency shall, immediately upon award of contract, make the evaluation report of the bid, and the contract agreement public through hoisting on the Authority's website as well as on procuring agency's website, if the procuring agency has such a website;

Provided where the procuring agency is convinced that disclosure of any information related to the award of a contract shall be against the public interest or may jeopardize national security, it can withhold only such information from public disclosure, subject to the prior approval of the Government.

Part II – PROCUREMENT OF GOODS, WORKS AND RELATED SERVICES

PROCUREMENT PLANNING

11. Procurement Plan

(1) Mandatory Provision of Procurement Plan - All procuring agencies shall devise a mechanism for planning in detail for all proposed procurements, determining the requirement of the procuring agency, within its available resources, and prepare an annual or a longer term rolling plan, detailing the procurement methods applicable for specific procurements;

(2) Review and Update - The procurement plan prepared for any project shall be reviewed and updated throughout the life of the project, such as estimates of time requirements, availability of funds, assumptions about institutional capacity, changing priorities and other factors that require plan adjustments for the success of the project. Such required adjustments will not invalidate the plan if made for improving the plan in the interests of the successful and timely completion of the project.

12. Limitation on Splitting or Regrouping of Proposed Procurement

(1) Save as otherwise provided and subject to the regulations made by the Authority, a procuring agency shall prepare, in accordance with Rule 11 above, all proposed procurements for each financial year and shall proceed accordingly without any splitting or regrouping of the procurements already grouped, allocated and scheduled in the Procurement Plan;

(2) The annual or longer rolling plan, as the case may be, thus prepared, will be posted in advance on the Authority's website as well as on website of the procuring agency, in case the procuring agency has its own website.

13. Specifications

(1) Specifications shall allow the widest possible competition and shall not favour any single contractor or supplier nor put others at a disadvantage. Specifications shall be generic and shall not include references to brand names, model numbers, catalogue numbers or similar classifications. However, if the procuring agency is convinced that the use of a reference to a brand name or a catalogue number is essential to complete an otherwise incomplete specification, such use or reference shall be qualified with the words "or equivalent".

(2) Procurement of used or reconditioned equipment, plant or machinery is not permissible in any case whatsoever.

14. Approval Mechanism – All procuring agencies shall provide clear authorization and delegation of powers for different categories of procurement and shall only initiate procurements once approval of the competent authorities concerned has been accorded.

METHODS OF PROCUREMENT

15. Types of Bidding

(1) Open Competitive Bidding - Open competitive bidding shall be the principal method of procurement, save as otherwise provided;

(2) There shall be two types of open competitive bidding, International Competitive Bidding and National Competitive Bidding.

A. International Competitive Bidding

i. International Competitive Bidding is open to all interested parties, firms or individuals, whether national or international, but subject to Rule 29;

ii. International Competitive Bidding shall be the default method of procurement for all procurements with an estimated cost equivalent to US $ 10 million or above;

iii. a procuring agency may opt for International Competitive Bidding for procurements below the estimated cost equivalent to US $ 10 million if it is convinced that technological sophistication, technical expertise or professional capability of the satisfactory level is not available within the country and the best value for money cannot be obtained, if competition is restricted to the domestic companies, firms or parties;

Provided that provisions of Rule 15 (2) (a) (iii) may be invoked only with prior approval of the Head of the Department.

B. National Competitive Bidding

i. National Competitive Bidding shall be the procedure wherein bidding is open only to interested national firms, companies or parties and international firms, companies or parties are not invited for the bidding.

ii. National Competitive Bidding shall be the principal method of procurement with an estimated cost below US $ 10 million or equivalent in local currency.

iii. a procuring agency may opt for National Competitive Bidding for procurements with an estimated cost equivalent to US $ 10 million or above, where the procuring agency is convinced that it is the most economical and timely way of procuring goods, works or services which, by their nature or scope are unlikely to attract foreign competition;

Provided that the Head of the Department of the procuring agency, while making decision to opt for the National Competitive Bidding shall record reasons and justifications for his decision.

16. Alternate Methods of Procurements

(1) A procuring agency may utilize following alternative methods of procurement of goods, services and works, namely:-

(a) Request for Quotations.

(i) request for quotation is the method based on comparing price quotations obtained from at least three suppliers, contractors, and service providers, in the case of services other than consulting services, to assure competitive prices;

(ii) a procuring agency shall engage in this method of procurement only if the following conditions exist;

(A) the cost of object of procurement is below the prescribed limit of one hundred thousand rupees and above the financial limit prescribed for petty purchase, as provided in clause (d);

(B) the object of procurement has standard specifications;

(C) the object of the procurement is purchased from the supplier offering the lowest price;

(D) requests for quotations shall indicate the description and quantity of the goods or specifications of works, as well as desired delivery, or completion time and place. Quotations may be submitted by letter, facsimile or by electronic means;

(E) the evaluation of quotations shall follow the same principles as applicable to open competitive bidding;

(b) Direct Contracting – This method means procurement from a single source without competition and shall only be applicable under any of the following conditions:

(i) standardization of equipment or spare parts, to be compatible with the existing equipment,

Provided that the competent authority certifies in writing the compatibility of the equipment or spare part(s) to be procured;

(ii) the required item(s) is of proprietary nature and obtainable only from one source,

Provided that the Head of the Department certifies in writing the proprietary nature of the item(s) to be procured;

(iii) the contractor responsible for a process design requires the purchase of critical items from a particular supplier as a condition of a performance guarantee;

(iv) 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 work subject to clause (e) below;

(v) where a change of supplier would oblige the procuring agency to acquire material having different technical specifications or characteristics and would result in incompatibility or disproportionate technical difficulties in operation and maintenance,

Provided that the competent authority certifies in writing the compatibility of the materials to be procured;

(vi) when the price of goods and works and service related thereto, is fixed by Government or any other authority, agency or body duly authorized by the Government, on its behalf;

(vii) for purchase of locally manufactured motor vehicle from local manufacturers or their authorized agents at manufacturer's price;

(viii) in cases of emergency;

Provided that the Head of the Department or any other officer not below BS-20 to whom such powers have been delegated by the Head of the Department, declares that a situation of emergency has arisen and reasons for making such a declaration shall be recorded in writing.

(c) Force Account – means construction by the use of the procuring agency's own personnel and equipment and shall only be used for the works under the following conditions;

(i) quantities of work to be done cannot be defined in advance;

(ii) works are small and scattered or in remote locations for which qualified construction firm(s) is unlikely to bid at reasonable prices;

(iii) works are required to be carried out without disrupting ongoing operations;

(iv) in case of emergencies ;

Provided that the competent authority declares that a situation of emergency has arisen and reasons for making such a declaration shall be recorded in writing.

(d) Petty Purchases - Procuring agencies may provide for petty purchases, where the object of the procurement is below the financial limit of twenty five thousand rupees. Such procurement shall be exempt from the requirements of bidding or quotation of prices;

Provided that procuring agencies shall ensure that the procurement of petty purchases is in conformity with the principles of procurement prescribed in Rule 4.

(e) Repeat Orders – means procurement of additional quantities of the item(s) from the original contractor or supplier, where, after the items originally envisaged for the project or scheme have been procured through open competitive bidding, and such additional quantities of the same item(s) of goods or works are needed to meet the requirements of the project or scheme;

Provided that;

(i) the cost of additional quantities of item(s) shall not exceed 15% of the original contract amount; and

(ii) the original supplier and contractor are willing to supply goods or carry out additional work on the same prices as agreed in the original contract; and

(iii) in case of goods, it shall be permissible only within the same financial year, and in case of works, during the currency of the project(s) or scheme(s).

NOTIFICATION AND ADVERTISEMENTS

17. Methods of Notification and Advertisement

(1) Procurements over one hundred thousand rupees and up to one million rupees shall be advertised by timely notifications on the Authority's website and may in print media in the manner and format prescribed in these rules.

[(1A) All procurement opportunities over one million rupees shall be advertised on the Authority's website as well as in the newspapers as prescribed.][13]

(2) The advertisement in the newspapers shall appear in at least three widely circulated leading dailies of English, Urdu and Sindhi languages.

(3) The notice inviting tender shall contain the following information:

(a) name, postal address, telephone number(s), fax number, e-mail address (if available) of the procuring agency;

(b) purpose and scope of the project;

(c) schedule of availability of bidding documents, submission and opening of bids, mentioning place from where bidding documents would be issued, submitted and would be opened;

(d) amount and manner of payment of tender fee and bid security;

(e) any other information that the procuring agency may deem appropriate to disseminate at this stage;

(4) In cases, the procuring agency has its own website; it shall also post all advertisements concerning procurement on that website as well;

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[13] Inserted vide SGA&CD Notification No. SORI(SGA&CD)2-30/2010 dated 8th October, 2013

(5) A procuring agency utilizing electronic media shall ensure that the information posted on the website contains all the information mentioned in sub-rule (3) above;

(6) In the case of international competitive bidding, the notice shall be advertised in two widely circulated local English language newspapers in accordance with sub-rules (1) (3) (4) and (5) above, and shall also be posted in English language on an internationally known website dedicated for the particular goods, works or services, or any widely circulated English language international newspaper.

18. [Response Time

(1) The procuring agency shall give due consideration to the scope, magnitude and nature of procurement while deciding the response time, which shall not be less than fifteen calendar days in case of National Competitive Bidding and forty-fivc days in case of international Competitive Bidding:

Provided that the Notice inviting Tenders (NIT) shall be hoisted on Authority's website in case of procurements up to rupees one million and published in newspapers in case of over rupees one million on or before the date of issuance of bidding documents".;][14]

19. Exceptions – Under following circumstances deviation from the requirements under Rules 17 and 18 is permissible;

(1) In cases of emergency, minimum time periods, specified in Rule 18 may be reduced subject to the prior approval with reasons to be recorded by the Head of Department or an officer not below BS-20 who has been delegated such powers;

(2) In cases of procurement related to national security, the requirement of advertisements and publication under Rule 17 may be waived, provided the Head of Department declares beforehand that such a publication could jeopardize national security objectives;

(3) The requirement of advertisement and publication under Rule 17 may be waived in a case of procurement, if it relates to disclosure of information, which is proprietary in nature or falls within the definition of intellectual property, which is available from a single source provided that, the approval of the Head of Department has been sought beforehand.

20. Provision of Bidding Documents

(1) The procuring agency shall provide the bidding documents to all interested bidders in accordance with the procedures and requirements specified in the Notice Inviting Tender;

(2) The procuring agency may charge a fee for bidding documents, which shall not exceed the cost of preparation and printing.

21. Contents of Bidding Documents

(1) The Bidding Documents shall include the following information:

(a) letter of invitation for bid;

(b) data sheet containing information about the assignment;

(c) instructions for preparing bids;

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[14] Substituted vide SGA&CD Notification No. SORI(SGA&CD)2-30/2010 dated 8th October, 2013

(d) amount and manner of payment of bid security and performance guarantee (where applicable);

(e) manner and place, date and time for submission of bidding documents;

(f) manner, place, date and time of opening of bids;

(g) method of procurement used;

(h) a detailed and unambiguous evaluation criteria;

(i) terms and conditions of the contract agreements, as far as already known by the procuring agency;

(j) Terms of Reference and technical specifications of goods, works or services to be procured, subject to Rule 13;

(k) manner in which tender price is to be assessed and computed, including information about tax liability;

(l) currency in which tender price is to be formulated and expressed;

(m) bid validity period;

(n) a copy of integrity pact to be signed by the parties (where applicable);

(o) any other information which is specified in regulations to be issued by the Authority.

(2) Any information, that becomes necessary for bidding or for bid evaluation, after the invitation to bid or issue of the bidding documents to the interested bidders, shall be provided in a timely manner and on equal opportunity basis. Where notification of such change, addition, modification or deletion becomes essential, such notification shall be made in a manner similar to the original advertisement.

(3) Procuring agencies shall use standard bidding documents as and when notified by the Authority;

Provided that bidding documents already in use of procuring agencies may be retained in their respective usage to the extent they are not inconsistent with these rules and till such time that the standard bidding documents are notified.

[(4)All procuring agencies shall hoist the bidding documents on Authority's website as well *as* on the website of procuring Agency, in case the procuring agency has its own website".][15]

21-A Evaluation criteria:- The procuring agencies shall formulate an appropriate evaluation criterion. listing all the relevant information against which a bid is to be evaluated and criteria of such evaluation shall form an integral part of the bidding documents. The failure to provide a clear and unambiguous evaluation criteria in the bidding documents shall amount to mis-procurement."][16]

[15] *Inserted vide SGA&CD Notification No. SORI(SGA&CD)2-30/2010 dated 8th October, 2013*
[16] *Inserted vide SGA&CD Notification No. SORI(SGA&CD)2-30/2010 dated 8th October, 2013*

22. **Extension of Time Period for Submission of Bids** –

The procuring agency may extend the deadline for submission of bids only, if one or all of the following conditions exist;

(1) Fewer than three bids have been submitted and procurement committee is unanimous in its view that wider competition can be ensured by extending the deadline. In such case, the bids submitted shall be returned to the Bidders un-opened;

(2) If the procuring agency is convinced that such extraordinary circumstances have arisen owing to law and order situation or a natural calamity that the deadline should be extended;

Provided that the advertisement of such extension in time shall be made in a manner similar to the original advertisement

23. Clarification and Modification of Bidding Documents

(1) An interested bidder, who has obtained bidding documents, may request for clarification of contents of the bidding document in writing, and procuring agency shall respond to such queries in writing within three calendar days, provided they are received at least five calendar days prior to the date of opening of bid;

Provided that any clarification in response to a query by any bidder shall be communicated to all parties who have obtained bidding documents;

(2) Procuring Agency shall re-issue the Notice Inviting Tenders, in accordance with Rules 17 and 18, if it is convinced that there is a material infirmity or ambiguity in the bidding documents, which cannot be addressed without modifying the contents of bidding documents.

24. Submission of Bids

(1) Bids shall be submitted on the place, date and time and in the manner specified in the tender notice and bidding documents and any bid submitted late due to any reason whatsoever, shall not be considered by the procurement committee;

(2) [The Bidders may submit bids on the bidding documents issued by the procuring agency or downloaded from the Authority's website along with tender foe if an)'by mail or by hand.][17]

25. Cancellation of Bidding Process

(1) A procuring agency may cancel the bidding process at any time prior to the acceptance of a bid or proposal;

(2) The procuring agency shall incur no liability towards the bidders, solely by virtue of its invoking sub-rule (1);

(3) Intimation of the cancellation of bidding process shall be given promptly to all bidders and bid security shall be returned along with such intimation.

(4) The procuring agency shall, upon request by any of the bidders, communicate to such bidder, grounds for the cancellation of bidding process, but is not required to justify such grounds;

26. Re-issuance of Tenders – The procuring agency may re-issue tenders in case, the bidding process has been cancelled, as provided in Rule 25 or one of the following conditions exist:

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[17] Substituted vide SGA&CD Notification No. SORI(SGA&CD)2-30/2010 dated 8th October, 2013

(1) Such an infirmity in the bidding documents has surfaced that the procuring committee recommends to the competent authority that the bids have to be invited afresh;

(2) The case has been declared as one of mis-procurement, in pursuance of [Rule 32 and 32-A][18];

Provided while re-issuing tenders, the procuring agency may change the specifications and other contents of bidding documents, as deemed appropriate.

PRE-QUALIFICATION AND DIS-QUALIFICATION OF SUPPLIERS, AND CONTRACTORS

27. Pre-qualification of Suppliers and Contractors

(1) A procuring agency, may engage in pre-qualification of bidders [XXX][19] in the following cases:

(a) in case of contracts for large and complex works and services related to, in which there are high costs of preparing detailed bids;

(b) in the contracts to be let under turnkey, design and build, or management contract;

(c) in case of expensive and technically complex equipment and works with a view to ensuring that invitations to bid are extended only to those who have adequate capabilities, competence and resources.

[(d) in case of drugs and services of complex nature.][20]

(2) 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) experience and past performance on similar assignments;

(b) capabilities with respect to construction or manufacturing facilities,

(c) financial capability;

(d) capabilities with respect to personnel, equipment, and plant;

(e) appropriate managerial capability; and

(f) any other factor that is relevant to the capability, competence and resources required for accomplishment of the assignment;

Provided that pre-qualification may be carried out only for specific procurement contract and shall be applicable only to that particular assignment.

28. Process of Pre-qualification -

(1) To prequalify for bidding on a specific contract or package:

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[18] Substituted vide SGA&CD Notification No. SORI(SGA&CD)2-30/2010 dated 8th October, 2013
[19] Omitted vide SGA&CD Notification No. SORI(SGA&CD)2-30/2010 dated 8th October, 2013
[20] Inserted vide SGA&CD Notification No. SORI(SGA&CD)2-30/2010 dated 8th October, 2013

(a) invitation to prequalify on specific contract or package shall be advertised and notified as per Rules 17 and 18.

(b) procuring agency shall provide a set of pre-qualification documents containing scope of contract, a clear set of requirements for qualification and evaluation criteria to any supplier or contractor, subject to payment of price, if any, which shall not exceed the limit, as prescribed in these Rules, and shall indicate the time and place where the documents can be obtained. Alternatively, if the procuring agency does not wish to issue pre-qualification documents, it shall include the scope of work and a clear set of requirements for pre-qualification and the evaluation criteria in the notice for pre-qualification.

(c) all applicants found capable of carrying out the assignments in accordance with the approved prequalification criteria shall be prequalified and invited to submit bids.

(d) verification of the information provided by the shortlisted applicants in the submissions for prequalification may be made. In case the information is found to be wrong or incorrect in any material way or the applicant is found to be lacking in the capability or resources to successfully perform the contract, the application shall not be prequalified.

(e) procuring agency shall promptly notify each and every applicant, whether or not it has been pre-qualified; and also make available to any person directly involved in the pre-qualification process, upon request, the names of all suppliers or contractors who have been pre-qualified.

(f) procuring agency shall, on written request of the applicant(s) communicate to the applicant(s) the reasons for not pre-qualifying them, though it shall not be obliged to justify these reasons.

(g) only suppliers or contractors, who have been pre-qualified shall be entitled to participate further in the procurement proceedings.

(2) The procuring agency, shall mention, in the pre-qualification documents;

(a) all information required for pre-qualification, pertaining to the factors mentioned at Rule 27 (2);

(b) instructions for preparation and submission of the pre-qualification documents;

(c) evaluation criteria;

(d) list of documentary evidence required from the applicants to demonstrate their respective qualifications;

(f) any other information that the procuring agency deems necessary for pre-qualification.

(3) In case of pre-qualification of consultants, provisions of Rules 73 and 74 shall apply.

29. Eligibility – All interested bidders, national or international, firms and individuals, shall be allowed to bid for any project where international competitive bidding is adopted;

(1) Competition may be restricted only in the following cases;

(a) as a matter of law or official regulations, commercial relations are prohibited with the bidder's country by the federal government; or

(b) a firm is blacklisted or debarred by the procuring agency, and the matter has been reported to the Authority, subject to Rule 35.

(2) Government owned enterprises or institutions may participate only if they can establish that they are;

(a) legally and financially autonomous; and

(b) operate under commercial law;

Provided that where government owned universities or research centers in the country are of a unique and exceptional nature, and their participation is critical to project implementation, they may be allowed to participate; and

(3) For the purposes of Part II of the Rules, bidders shall include all those contractors or suppliers and providers of services related thereto or consultants that are registered or incorporated in Pakistan, irrespective of the nationality of their owners and of their professional staff;

(4) There shall be no enlistment or registration of contractors, suppliers and consultants by any procuring agency, and bidding shall not be restricted in any manner, except as otherwise provided in these Rules;

Provided that registration with professional institutions in respective fields shall apply as required by the law.

30. Disqualification of Suppliers, Contractors and Consultants

(1) The procuring agency shall disqualify a supplier, consultant or contractor, whether already pre-qualified or not, if it finds at any time, that the information submitted by him concerning his qualification and professional, technical, financial, legal or managerial competence as supplier, consultant or contractor, was false and materially inaccurate or incomplete; or

(2) At any stage has indulged in corrupt and fraudulent practices, as defined in these rules;

(3) A supplier, contractor or consultant being aggrieved by the decision of the procuring agency regarding disqualification may seek relief through the mechanism of grievance redressal, as provided under Rule 31.

REDRESSAL OF GRIEVANCES AND SETTLEMENT OF DISPUTES

31. Mechanism for Redressal of Grievances

(1) The procuring agency shall constitute a committee for complaint redressal comprising odd number of persons, with appropriate powers and authorizations, to address the complaints of bidders that may occur during the procurement proceedings.

(2) The committee shall be headed by head of the procuring agency or an official of the procuring agency, at least one rank senior to the head of the procurement committee and shall include the following;

(a) District Accounts Officer, or his representative, in case of the local governments or provincial line departments at district level, or a representative of the Accountant General, Sindh in case of Government departments at the provincial level;

(b) an independent professional from the relevant field concerning the procurement process in question, to be nominated by the head of procuring agency;

(3) [Any bidder being aggrieved by any act or decision of the procuring agency after 1be issuance of notice inviting render may lodge a written complaint;][21]

(4) The complaint redressal committee upon receiving a complaint from an aggrieved bidder may, if satisfied;

(a) prohibit the procurement committee from acting or deciding in a manner, inconsistent with these rules and regulations;

(b) annul in whole or in part, any unauthorized act or decision of the procurement committee; and

[(bb) recommend to the Head of Department that the case be declared a mis-procurement if material violation of Act, Rules, Regulations, orders, instructions or any other law relating to public procurement. has been established; and;][22]

(c) reverse any decision of the procurement committee or substitute its own decision for such a decision;

Provided that the complaint redressal committee shall not make any decision to award the contract.

(5) [The complaint redressal committee shall announce its decision within seven days and intimate the same to the bidder and the Authority within three working days. If the committee fails to arrive at the decision within seven days, the complaint shall stand transferred to rhe Review Committee which shall dispose of the complaint in accordance with the procedure laid down in rule 32;][23]

(6) The Procuring Agency shall award the contract after the decision of the complaint redressal committee;

(7)

[Mere fact of lodging of a complaint shall not warrant suspension of the procurement proceedings;

Provided that in case of failure of the complaint redressal committee to decide the complaint; the procuring agency shall not award the contract."]

(8) A bidder not satisfied with decision of the procuring agency's complaints' redressal committee may lodge an appeal to the Chief Secretary through the Authority, who shall refer the matter to a review panel as per Rule 32;

(9) A bidder may file an appeal to the Chief Secretary provided;

(a) that the bidder has exhausted his complaint to the complaint redressal committee; and

(b) that he has not withdrawn the bid security deposited by him during the procurement process.

(10) The bidder must submit the appeal to the Chief Secretary with the following documents:

(a) a letter stating his wish to appeal to the Review Panel and the nature of complaint;

(b) a copy of the complaint earlier submitted to the complaint redressal committee of the Department and all supporting documents in a sealed envelope; and

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[21] Amended vide SGA&CD Notification No. SORI(SGA&CD)2-30/2010 dated 8th October, 2013
[22] Inserted vide SGA&CD Notification No. SORI(SGA&CD)2-30/2010 dated 8th October, 2013
[23] Amended vide SGA&CD Notification No. SORI(SGA&CD)2-30/2010 dated 8th October, 2013

(c) non-refundable complaint registration fee in the form of a Pay Order in favour of the Authority in the amount specified in Appendix A.

(11) Upon receipt of an appeal and registration fee, the Chief Secretary shall select a Review Panel to examine the complaint. Simultaneously, the Authority shall inform the bidder and the Head of the concerned Department of the action taken by the Chief Secretary.

(12) On receipt of reference from the Chief Secretary, the Chairperson of the Review Panel shall convene a meeting of the review panel within five working days.

(13) Unless the Review Panel recommends dismissal of the complaint being frivolous, in which case the bidder shall loose the bid security deposited with the procuring agency, the Review Panel may:

(a) propose rejection of the complaint, stating its reasons;

(b) state the rules or principles that govern the subject matter of the complaint;

(c) point out the infirmities and breach of rules and regulations by the procuring agencies;

(d) suggest annulment in whole or in part of a non-compliant act or decision of a procuring agency, other than any act or decision bringing the procurement contract into force;

(e) if the procuring agency is in breach of its obligations under the Act, Rules or Regulations, suggest the payment of compensation by the officer(s) responsible for mis-procurement for cost incurred by the bidder on preparation of bid, including the cost of the complaint registration fee paid by the complainant; or

(f) recommends that the procurement proceedings may be terminated, in case the procurement contract has not been signed.

(14) It shall be mandatory for both, the complainant and the procuring agency to appear before the Review Panel as and when called and produce documents, when so required. The Review Panel shall issue the notice of appearance to the Head of the Department for its service who shall ensure the attendance of the Head of Procuring Agency along with relevant record. In case of failure of Head of Procuring Agency to appear before review panel despite service, the Authority shall bring the matter to the notice of Chief Secretary. In case the complainant fails to appear twice, despite service the reference may be decided ex-parte. The Review Panel shall hear the parties and give its recommendations to the Authority within thirty days of receipt of reference. In case, more time is required, the Review Panel may seek extension from the Chief Secretary through the Authority enumerating the reasons for delay. The Authority shall submit these recommendations to the Chief Secretary who shall decide the appeal keeping in view the recommendations of the Review Panel;

Provided that the Chief Secretary may refer the matter back to the Review Panel, if there is some ambiguity or vagueness in the recommendations and a clarification is to be sought. The Review Panel shall clarify the matter within seven calendar days, following which the Chief Secretary would decide the matter;

(15) The decision of the Chief Secretary shall be final and the procuring agency shall act upon such findings. After the decision has been issued, the complaint and the decision shall be hoisted by the Authority on its website within three working days;

Provided that no information shall be disclosed if its disclosure would be against the public interest or may jeopardize national security.

32. Appeal to the Review Committee

(1) A bidder not satisfied wi1h decision of the procuring agency's complaints redressal committee may lodge an appeal to the Review committee: provided that he has not withdrawn the bid security, if any, deposited by him.

(2) The Review Committee shall comprise the following:

(a) Managing Director;
(b) Director General Audit Sindh or his nominee not below the rank of BS-19;
(c) {c)two private members represented on the SPPRA Board.
(d) an independent professional having expertise of relevant field concerning the procurement in question.

(3) The Managing Director shall be the Chairperson of the Review Committee and the private members shall be selected by the SPPR.A Board for a period not exceeding two years:

(4) The independent professional shall be nominated by the Managing Director for each reference and paid remuneration for attending the meeting of Review Committee at a rate prescribed by the Authority from time to Lime;

(5) The bidder shall submit following documents Lo the Review Committee:-

(a) a letter stating his wish to appeal to the Review Committee and the nature of complaint;
(b) a copy of the complaint earlier submitted to the complaint redrcssal committee of tile Department and all supporting documents;
(c) Copy of the decision of Procuring Agency / Complaint Redressal Committee.

(6) On receipt of appeal, the Chairperson shall convene a meeting of the Review Committee within seven working days;

(7) Unless the Review Committee recommends dismissal of an appeal being frivolous, in which case the bidder may lose the bid security deposited with the procuring agency, the Review Committee may -

(a) reject the reference, stating its reason;

(b) state the rules or principles that govern the subject matter of reference;

(c) point out the infirmities and breach of roles and regulations by the procuring agency;
(d) annul in whole or in part of a non-compliant act *or* decision of a procuring agency, other than any act or decision bringing the procurement contract into force;
(e) if the procuring agency is in breach of its obligations under the Act, Rules or Regulations, order the payment of compensation by the officer(s) responsible for mis-procurement for cost Incurred by the bidder on preparation of bid; or

(f) direct that the procurement proceedings may be terminated. in case the procurement contract has not been signed,
(g) declare the case to be one of mis-procurement if material violation of Act, Rules, Regulations, orders. instructions or any other law relating to public procurement bas been established.

(8) It shall be mandatory for the appellant and the head of procuring agency or his nominee not below the rank of BS-19 to appe.ar before the Review Committee as and when called and produce documents, if required.

(9) In case the appellant fails to appear twice despite the service of notice of appearance, the appeal may be decided ex-pane.

(10) The Review Committee shall bear the parties and announce its decision within ten working days of submission of appeal

(11) The decision of Review Committee shall be final and binding upon the procuring agency. After the dccis.ion has been announced, the appeal and the decision thereof shall be hoisted by the Authority on its website.][24]

32A. Declaration of Mis-procurement and its consequences,-

(1) Notwithstanding anything contained in Rule-32 (7) (g):

(a) The Head of the Department on his own initiation or on recommendation or the Complaint Redressal Committee of the Department may declare the case to be of mis-procurement, if any material violation of provisions of the Act, Rules. Regulations, orders. instructions or any other law relating to public procurement, bas beenestablished.

The Authority may take notice of any material violation of provisions of the Act. Rules, Regulations, orders, instructions or any other law relating co public procurement and declare the case to be mis-procurement if such violation has been established.

(2) On declaration of mis-procurement; the head of the procuring agency, the Authority or the Review Committee shall refer t he case to the Competent Authority for initiation of disciplinary proceedings against the officials of the procuring agency responsible for mis-procurement and may also refer the matter to the Sindh Enquiries and An t.i-Corrup1ion Establishment for initiating action against such officials.][25]

33. Matters not subject to Appeal or Review – The following actions of the procuring agency shall not be subject to the appeal or review:

(1) Selection method adopted by the procurement committee;

(2) Decision by the procuring agency under Rule 25 to cancel the bidding process.

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[24] Amended vide SGA&CD Notification No. SORI(SGA&CD)2-30/2010 dated 8th October, 2013
[25] Inserted vide SGA&CD Notification No. SORI(SGA&CD)2-30/2010 dated 8th October, 2013

34. Arbitration

(1) After coming into force of the procurement contracts, disputes between the parties to the contract shall be settled by arbitration;

(2) The procuring agencies shall provide for a method of arbitration in the procurement contract, not inconsistent with the laws for the time being in force in Pakistan.

35. Blacklisting of Suppliers, Contractors and Consultants

(1) The following shall result in blacklisting of suppliers, contractors, or consultants, individually or collectively as part of consortium:

(a) conviction for fraud, corruption, criminal misappropriation, theft, forgery, bribery or any other criminal offence;

(b) involvement in corrupt and fraudulent practices while obtaining or attempting to obtain a procurement contract;

(c) final decision by a court or tribunal of competent jurisdiction that the contractor or supplier is guilty of tax evasion;

(d) willful failure to perform in accordance with the terms of one or more than one contract;

(e) failure to remedy underperforming contracts, as identified by the procuring agency, where underperforming is due to the fault of the contractor, supplier or consultant;

(2) Procuring agency may, on its own motion, or information provided by any party, carry out an investigation to determine, whether there is sufficient cause for blacklisting a contractor, consultant or supplier. If the procuring agency is satisfied that such a cause exists, it shall initiate the process of blacklisting in accordance with the procedure laid down in regulations to be issued by the Authority;

(3) As a result of the scrutiny process, as mentioned above in sub-rule (2), the procuring agency may take one of the following decisions;

(a) contractor or consultant or supplier may be blacklisted;

(b) contractor or consultant or supplier may be debarred temporarily, specifying the time period;

(c) contractor or consultant or supplier may be blacklisted if he fails to take the specified remedial actions within a specified time period;

Provided that the procuring agency shall duly publicize and communicate its decision to the Authority, other Government departments, and also hoist on its own website.

[(4) Any party being aggrieved by the decision of the procuring agency may submit an appeal to the Authority, which shall refer the matter to the Review Committee, which shall decide the matter as provided in sub-rules (5) to (11) of rule 32.;][26]

(5) [XXX][27]

36. Reservations and Preference

[26] *Amended vide SGA&CD Notification No. SORI(SGA&CD)2-30/2010 dated 8th October, 2013*
[27] *Omitted vide SGA&CD Notification No. SORI(SGA&CD)2-30/2010 dated 8th October, 2013*

(1) Procuring agencies shall allow all interested bidders to participate in procuring procedure without regard to nationality, except in cases in which any procuring agency decides to limit such participation to national bidders only or prohibit participation of bidders of some nationalities, in accordance with these rules or policy of the Federal Government;

(2) Procuring agencies shall allow for a preference to domestic or national suppliers, contractors or consultants in accordance with the policies of the Government. The magnitude of price preference to be accorded shall be clearly mentioned in the bidding documents under the bid evaluation criteria.

37. Bid Security

(1) The procuring agency shall require the bidders to furnish a bid security not below one percent and not exceeding five percent of the bid price, which shall remain valid for a period of 28 days beyond the validity period for bids, in order to provide the procuring agency reasonable time to act, if the security is to be called;

(2) Bid security shall be released to the unsuccessful bidders once the contract has been signed with the successful bidder or the validity period has expired.

38. Bid Validity

(1) A procuring agency, keeping in view nature of procurement, shall subject the bid to a validity period, which shall be specified in the bidding document and shall not be more than 90 days in case of National Competitive Bidding and 120 days in case of International Competitive Bidding;

(2) Extension of bid validity may be allowed subject to approval by the competent authority of the procuring agency, and with reasons to be recorded in writing;

Provided that if validity period has to be extended due to some slackness on the part of procuring agency, the competent authority shall fix responsibility and take appropriate disciplinary action;

(3) After obtaining such approval, the procuring agency, shall request in writing all bidders to extend the bid validity period. Such a request shall be made before the date of expiry of the original bid validity period;

(4) Such an extension shall not be for more than [XXX][28] the original period of bid validity;

(5) In case the Procuring Agency fails to finalize the bid evaluation within the extended time, the bids shall stand cancelled and a fresh bidding process shall be initiated;

(6) Whenever an extension of bid validity period is requested, a bidder shall have the right to refuse to grant such an extension and withdraw his bid and bid security shall be returned forthwith;

(7) Bidders who;

(a) agree to extension of the bid validity period shall also extend validity of the bid security for the agreed extended period of the bid validity;

(b) agree to the procuring agency's request for extension of bid validity period shall neither be requested nor permitted to change the price or other conditions of their bids.

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[28] Omitted vide SGA&CD Notification No. SORI(SGA&CD)2-30/2010 dated 8th October, 2013

39. Performance Security

(1) Procuring Agency shall, in all procurement of goods, works and services, carried out through open competitive bidding, require security in the form of pay order or demand draft or bank guarantee, an amount sufficient to protect the procuring agency in case of breach of contract by the contractor or supplier or consultant, provided that the amount shall not be more than 10% of contract price;

(2) The security shall be provided in an appropriate form and amount, as provided in the bidding documents;

(3) Validity of performance security shall extend at least ninety days beyond the date of completion of contract to cover defects liability period or maintenance period subject to final acceptance by the procuring agency.

40. Force Majeure – The conditions of contract shall stipulate that failure on the part of the parties to perform their obligations under the contract will not be considered a default if such failure is the result of an event of force majeure as defined in the conditions of contract.

OPENING, EVALUATION AND REJECTION OF BIDS

41. Opening of Bids

(1) The date for opening of bids and the last date for the submission of bids shall be the same, as given in the bidding documents and in the Notice Inviting Tender;

(2) Subject to provisions of Rule 18, in case, the two dates are different, the date and time, given in the bidding documents shall apply;

(3) The bids shall be opened within one hour of the deadline for submission of bids;

(4) All bids shall be opened publicly in the presence of all the bidders, or their representatives, who may choose to be present in person, at the time and place announced in the invitation to bid;

(5) The procuring agency shall read aloud the name of the bidder and total amount of each bid, and of any alternative bids if they have been permitted, shall be read aloud and recorded when opened;

(6) All bidders in attendance shall sign an attendance sheet;

(7) All bids submitted after the time prescribed as well as those not opened and read out at bid opening, due to any procedural flaw, shall not be considered, and shall be returned without being opened;

(8) The official chairing procurement committee shall encircle the rates and all the members of procurement committee shall sign each and every page of financial proposal;

(9) The procurement committee shall issue the minutes of the opening of the tenders and shall also mention over writing or cutting, if any.

42. Evaluation of bids

(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.

43. Clarification of bids

(1) No bidder shall be allowed to alter or modify his bid(s) after the expiry of deadline for the receipt of the bids;

Provided that the procuring agency may ask the bidders for clarifications needed to evaluate the bids but shall not permit any bidder to change the substance or price of the bid;

(2) Any request for clarification in the bid, made by the procuring agency, shall invariably be in writing. The response to such request shall also be in writing.

44. Discriminatory and difficult conditions – Save as otherwise provided, no procuring agency shall introduce any condition which discriminates among bidders. In ascertaining the discriminatory 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.

45. Announcement of evaluation reports – Procuring agencies shall announce the results of bid evaluation in the form of a report giving reasons for acceptance or rejection of bids. The report shall be hoisted on website of the Authority and that of the procuring agency if its website exists and intimated to all the bidders at least seven (07) days prior to the award of contract.

46. Procedures of open competitive bidding – Save as otherwise provided in these rules, the following procedures shall be permissible for open competitive bidding;

(1) Single Stage – One Envelope Procedure

(a) Notice Inviting Tenders and bidding documents of this method shall contain the following eligibility criteria;

(i) relevant experience;

(ii) turn-over of at least last three years;

(iii) registration with Income Tax, Sales Tax and Pakistan Engineering Council (where applicable);

(iv) any other factor deemed to be relevant by the procuring agency subject to provision of Rule 44;

(b) each bid shall comprise one single envelope containing the financial proposal and required information mentioned at clause (a) above;

(c) all bids received shall be opened and evaluated in the manner prescribed in the Notice Inviting Tenders or bidding document.

(2) Single stage – two envelope procedure

(a) bid shall comprise a single package containing two separate envelopes. Each envelope shall contain separately the financial proposal and the technical proposal;

(b) envelopes shall be marked as "FINANCIAL PROPOSAL" and "TECHNICAL PROPOSAL" in bold and legible letters to avoid confusion;

(c) initially, only the envelope marked "TECHNICAL PROPOSAL" shall be opened;

(d) envelope marked as "FINANCIAL PROPOSAL" shall be retained in the custody of the procuring agency without being opened;

(e) procuring agency shall evaluate the technical proposal in a manner prescribed in advance, without reference to the price and reject any proposal which does not conform to the specified requirements;

(f) no amendments in the technical proposal shall be permitted during the technical evaluation;

(g) financial proposals of technically qualified bids shall be opened publicly at a time, date and venue announced and communicated to the bidders in advance;

(h) financial proposal of bids found technically non-responsive shall be returned un-opened to the respective bidders; and

(j) bid found to be the lowest evaluated or best evaluated bid shall be accepted.

(3) Two Stage Bidding Procedure

(a) First Stage;

(i) bidders are invited to submit, according to the required specifications, a technical proposal without price, which shall be subject to technical as well as commercial clarifications and adjustments;

(ii) technical proposal shall be evaluated in accordance with the specified evaluation criteria and may be discussed with all the bidders together regarding any technical features that may require technical as well as commercial clarifications and adjustments;

(iii) after such discussions, all the bidders shall be permitted to revise their respective technical proposals to meet the requirements of the procuring agency;

(iv) procuring agency may revise, delete, modify or add any aspect of the technical requirements or evaluation criteria, or it may add new requirements or criteria not inconsistent with these rules;

Provided that such revisions, deletions, modifications or additions are communicated to all the bidders equally at the time of invitation to submit final bids, and that sufficient time is allowed to the bidders to prepare their revised bids;

Provided further that such allowance of time shall not be less than fifteen days in the case of National Competitive Bidding and [forty-five days][29] in the case of International Competitive Bidding;

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[29] Substituted vide SGA&CD Notification No. SORI(SGA&CD)2-30/2010 dated 8th October, 2013

(v) The bidders not willing to conform their respective bids to the procuring agency's technical requirements may be allowed to withdraw from the bidding without imposition of any penalty.

(b) Second Stage;

(i) bidders shall be allowed to amend their technical proposals in order to ensure conformance to the same technical standards;

(ii) bidders submit the revised technical proposals along with financial proposals;

(iii) the financial proposals of only those bidders whose original or revised technical proposals are found to be conforming to the agreed technical standards and requirements, shall be opened at a time, date and venue announced and communicated to the bidders in advance;

(iv) the revised technical proposals and the financial proposals shall be evaluated in the manner prescribed above. The bid found to be the lowest evaluated bid shall be accepted;

Provided that in setting the date for the submission of the revised technical proposal and financial proposal a procuring agency shall allow sufficient time to the bidders to incorporate the agreed upon changes in the technical proposal and prepare their financial proposals accordingly.

(4) Two Stage - Two Envelope Bidding Procedure

(a) First Stage

(i) bid shall comprise a single package containing two separate envelopes. Each envelope shall contain separately the financial proposal and the technical proposal;

(ii) 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) envelope marked as "FINANCIAL PROPOSAL" shall be retained in the custody of the procuring agency without being opened;

(v) technical proposal shall be discussed with all the bidders or their representatives present together with reference to the procuring agency's technical requirements;

(vi) the bidders willing to meet the requirements of the procuring agency shall be allowed to revise their technical proposals following these discussions;

(vii) bidders not willing to conform their technical proposal to the revised requirements of the procuring agency shall be allowed to withdraw their respective bids without forfeiture of their bid security;

(b) Second Stage

(i) 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 revised technical requirement;

(ii) 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 agency;

Provided that in setting the date for the submission of the revised technical proposal and supplementary financial proposal a procuring agency 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) procuring agency shall evaluate the whole proposal in accordance with the evaluation criteria and the bid found to be the lowest evaluated bid shall be accepted.

47. Conditions for Use of Various Procedures

(1) **Single Stage One Envelope Bidding Procedure** shall be used as the standard bidding procedure for procurement of goods, works and services of simple and routine nature and where no technical complexity or innovation is involved;

[(2) **Single Stage Two Envelope Bidding Procedure** shall be used for goods and services where the bids are to be evaluated on technical and financial grounds and price is taken into account after technical evaluation;][30]

(3) **Two Stage Bidding Procedure** shall be adopted in large and complex contracts where technically unequal proposals are likely to be encountered or where the procuring agency is aware of its options in the market but, for a given set of performance requirements, there are two or more equally acceptable technical solutions of machinery or equipment or manufacturing plant available to the procuring agency][31]; and

[(4) **Two Stage Two Envelope Bidding** Method shall be used for procurement where alternate technical proposals are possible, such as certain type of machinery or equipment or manufacturing plant.][32]

ACCEPTANCE OF BIDS AND AWARD OF PROCUREMENT CONTRACTS

48. Acceptance of Bids – Even when only one bid is submitted, the bidding process may be considered valid, if the bid was advertised in accordance with rules, and prices are comparable to the prices or rates of the last awarded contract or the market prices.

49. Award of Contract – 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.

50. Publication of the Award of Contract – Within seven days of the award of contract, procuring agency shall publish on the website of the Authority and on its own website, if such a website exists, the results of the bidding process, identifying the bid through procurement identifying number, if any, and the following information:

(1) Evaluation Report;

(2) Form of Contract and Letter of Award;

(3) Bill of Quantities or Schedule of Requirement.

51. Debriefing

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[30] Amended vide SGA&CD Notification No. SORI(SGA&CD)2-30/2010 dated 8th October, 2013
[31] Amended vide SGA&CD Notification No. SORI(SGA&CD)2-30/2010 dated 8th October, 2013
[32] Amended vide SGA&CD Notification No. SORI(SGA&CD)2-30/2010 dated 8th October, 2013

(1) A bidder may ask the procuring agency for reasons for non-acceptance of his bid and may request for a debriefing meeting and procuring agency shall give him the reasons for such non-acceptance, either in writing or by holding a debriefing meeting with such a bidder.

(2) The requesting bidder shall bear all the costs of attending such a debriefing.

52. Bar on Negotiations – Save as otherwise provided there shall be no negotiations with the bidder having submitted the lowest evaluated bid or with any other bidder.

53. Confidentiality – The procuring agency shall keep all information regarding the bid evaluation confidential until the time of announcement of evaluation report in accordance with the requirements of Rule 45.

54. On Account Payments – All procuring agencies shall make payments to suppliers, consultants and contractors against their invoices or running bills within the time given in the conditions of the contract,

55. Entry into Force of the Procurement Contract – A procurement contract shall come into force when the procuring agency signs a contract, the date on which the signatures of both the procuring agency and the successful bidder are affixed to the written contract. Such affixing of signatures shall take place within the time prescribed in the bidding documents.

Provided that where coming into force of a contract is contingent upon fulfillment of a certain condition(s), the contract shall take effect from the date whereon such fulfillment takes place.

56. [XXX][33]

57. Closing of Contract

(1) Except for defect liability or maintenance by the supplier, consultant or contractor, as specified in the conditions of contract, performance of the contract shall be deemed close on the issue of overall delivery certificate, certificate of completion of deliverables, 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 supplier or contractor to submit final bill and the procuring agency to carry out any inspection of goods, works or services related thereto, as provided in the contract agreement and auditors to do substantial audit.

(2) In case of defect liability or maintenance periods, defect liability certificate shall be issued within thirty days of the expiry of the said period enabling the supplier or contractor to submit the final bill.

(3) Except for unsettled claims, which shall be resolved through arbitration, and shall be paid within the time given in the conditions of contract.

Part III – PROCURING CONSULTING SERVICES GENERAL PROVISIONS

58. Applicability

(1) Subject to provisions of Part I and II, Part III shall apply only to consulting services;

(2) In case of any conflict in provisions or their interpretation within the rules, for consulting services, rules under this part shall take precedence over rules in other parts.

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[33] Omitted vide SGA&CD Notification No. SORI(SGA&CD)2-30/2010 dated 8th October, 2013

59. [XXX][34]

60. [XXX][35]

61. Selection of Consultancy Services –

The selection shall be guided by the following considerations:

(1) Best quality of services available;

(2) Need for economy and efficiency;

(3) Need to give all qualified consultants an equal opportunity to compete;

(4) Encouragement of local consultants without any unfair competitive advantage;

(5) Transparency in the selection process.

62. Bar on hiring in cases of Conflict of Interest – Without limitations on the generality of the foregoing, consultants shall not be hired if there is a conflict of interest, as defined in these rules.

63. Hiring of Government Officials and Academics – Government officials and civil servants may be hired as consultants only if:

(1) They are on leave of absence without pay;

(2) They are not being hired by the agency they were working for, six months prior to going on leave; and

(3) Their employment would not give rise to any conflict of interest.

64. Equal Access to Information – The procuring agency shall make available information to all the bidders for consulting services on an equal opportunity basis.

65. Rights and Obligations of the Procuring Agency and Consultants – Rights and obligations of the procuring agency and the consultant shall be governed by General and Special conditions of contract signed between the procuring agency and the consultant.

66. Steps in the Selection Process – Depending on the selection method adopted, the procuring agency shall undertake the following steps but not limited to:

(1) Preparation of the Terms of Reference of the assignment;

(2) Preparation of the cost estimate or budget of the assignment;

(3) Public advertisement of Request for Expressions of Interest;

(4) [Short-listing of consultants, if deemed necessary;][36]

(5) Preparation and issuance of the Request for Proposal to the shortlisted consultants;

(6) Preparation and submission of proposals by consultants;

(7) Evaluation of technical proposals as per criteria given in the Request for Proposal;

(8) Opening and evaluation of financial proposals as per criteria given in the Request for Proposal;

(9) Contract negotiations, as provided in the selection method;

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[34] Omitted vide SGA&CD Notification No. SORI(SGA&CD)2-30/2010 dated 8th October, 2013

[35] Omitted vide SGA&CD Notification No. SORI(SGA&CD)2-30/2010 dated 8th October, 2013

[36] Amended vide SGA&CD Notification No. SORI(SGA&CD)2-30/2010 dated 8th October, 2013

(10) Award and signing of the contract between the procuring agency and the consultant;

67. Consultant Selection Committee – Every procuring agency, for the selection of consultant(s), shall set up a Consultant Selection Committee, which shall consist of the following:

(1) Consultant Selection Committee shall be headed by a gazetted officer not below the rank of BS-19 and, if not available, the officer of the highest grade available in case of administrative departments, autonomous and semi autonomous bodies.

(2) Project or programme directors, coordinators or managers shall head Consultant Selection Committees of the respective projects or programmes;

(3) **Members;**

(a) nominee of the Planning & Development Department not below the rank of BS-18;

(b) nominee of the Finance Department not below the rank of BS-18;

(c) a representative of the procuring agency not below the rank of BS-18 to act as member and secretary;

(d) one technical member from the concerned departments for consultation having adequate experience in the relevant field not below the rank of BS-18 or equivalent;

(e) co-opted member(s) – The Consultants Selection Committee, with the approval of its Chairperson, can co-opt up to two members, having adequate technical knowledge and experience in the relevant field, for providing technical input to the committee. The co-opted members shall have no voting rights.

Provided that co-opted members shall have no conflict of interest in the procurement process.

68. Quorum – The chairman, representatives of the Finance Department, and the Planning and Development Department shall form the quorum for conducting the business of the Consultants Selection Committee.

69. Consultants Selection Committee for Local Government Institutions

(1) In case of District Governments, the Executive District Officer of the concerned department shall head the Consultants Selection Committee, with the following members:

(a) Executive District Officer, Finance & Planning or his representative not below the rank of BS-18 as member;

(b) District Officer of the concerned procuring department as member and secretary;

(c) [XXX][37]

(2) Consultants Selection Committee, with the approval of its Chairperson, can co-opt up to two members, having adequate technical knowledge and experience in the relevant field, for providing technical input to the committee;

Provided that the co-opted members shall have no conflict of interest in the procurement proceedings and shall have no right to vote;

[37] *Omitted vide SGA&CD Notification No. SORI(SGA&CD)2-30/2010 dated 8th October, 2013*

(3) The chairman, representative of the Finance and Planning Department, and one private member shall form the quorum for conducting the business of the Consultants Selection Committee.

(4) In case of Town or Taluka Municipal Administrations, Town or Taluka Officer of the concerned department concerned shall head the Consultants Selection Committee, with the following members:

(a) Town or Taluka officer, Infrastructure as member;

(b) Accounts officer of the Taluka or Town Municipal Administrator as member;

(c) two members from civil society having the professional background in the relevant field;

(d) Consultants Selection Committee, with the approval of its chairperson, can co-opt up to two members, having adequate technical knowledge and experience in the relevant field, for providing technical input to the committee. The co-opted members shall have no voting rights;

Provided that the co-opted members shall have no conflict of interest in the procurement process.

70. Decision by Simple Majority –

All decision of the Consultants Selection Committee shall be made by simple majority.

71. Functions and Responsibilities of the Committee – The Consultants Selection Committee shall perform the following functions:

(1) Approval of Request For Proposal before issuance;

(2) Short listing of consultants, responding to the Request for Expression of

Interest, where applicable, in accordance with the criteria mentioned in Request for Expression of Interest;

(3) Evaluation of technical and financial proposals, according to the selection method and evaluation criteria, mentioned in the Request for Proposal;

(4) Finalization of recommendation based on evaluation as mentioned at sub-rule (3) above.

72. Methods for Selection of Consultants – The selection system shall be determined by the procuring agency prior to issuance of the Request for Proposals from interested consultants. A procuring agency may adopt one of the following methods for selection of consultants, keeping in view nature of the assignment:

(1) Least Cost Selection Method

(a) this method shall be adopted for assignments of standard or routine nature where well-established practices and standards exist;

(b) financial proposals of only technically qualified firms shall be opened. The firm with the lowest quoted cost or bid shall be selected.

(c) procuring agency may adopt any other method as deemed fit with reason to be recorded in writing by the competent authority.

(2) Quality Based Selection Method –

(a) this method shall be used only in case of highly specialized, innovative and complex assignments, where quality is the only factor taken into consideration.

(b) in Quality Based Selection method the technical proposal which attains the highest score according to the criteria mentioned in the bidding documents shall be selected without any consideration for cost.

(c) the selected firm shall be asked to submit its financial proposal and invited to negotiate the financial proposal and the contract.

(3) Quality and Cost Based Selection Method - This method shall be used only where;

(a) the Terms of Reference are well-defined and Quality is of prime consideration, while cost is a secondary consideration;

(b) the firm which attains the highest combined weighted technical and financial score according to the criteria mentioned in the bidding documents shall be selected.

(4) Direct Selection Method - This method shall be used only if all or any of the following conditions exists:

(a) for tasks which are natural continuation of previous assignment and where continuity of technical services is required[:][38]

[Provided that the cost of additional assignment does not exceed fifteen per cent of the cost of previous assignment.][39]

(b) for assignments worth less than rupees one hundred thousand;

(c) in cases of emergency [with the approval of competent authority and for reasons to be recorded in writing.][40]

(d) where only one consultant is qualified or has experience of exceptional worth.

(5) Fixed Budget

(a) this method shall be used only when all of the following conditions exist:

(i) assignment is simple;

(ii) can be precisely defined;

(iii) budget is fixed;

(b) the Request for Proposal shall indicate the available budget. Proposals that exceed the indicated budget shall be rejected;

(c) the ranking shall be based only on evaluation of technical proposals of the qualified bidders.

(6) Design Contest - This method shall be used only for projects where aesthetic component is of prime consideration. The procuring agency shall invite consultants to submit a financial proposal and present a plan or design for the project based on a concept or criteria provided by it. The financial proposal of the top-ranked consultant shall only be opened.

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[38] Amended vide SGA&CD Notification No. SORI(SGA&CD)2-30/2010 dated 8th October, 2013
[39] Amended vide SGA&CD Notification No. SORI(SGA&CD)2-30/2010 dated 8th October, 2013
[40] Amended vide SGA&CD Notification No. SORI(SGA&CD)2-30/2010 dated 8th October, 2013

(7) Consultant's Qualifications Selection Method

(a) this method shall apply only to small consultancies for which the cost of a full-fledged selection process would not be justified.

(b) consulting firm is selected at the stage of Expression of Interest on the basis of criteria mentioned in the Request for Expression of Interest.

The selected firm is asked to submit a technical and financial proposal, in single envelope, and then invited to negotiate the contract.

(8) Selection Process of Individual Consultants

(a) this method shall be adopted only if all or any of the following conditions exist:

(i) the scope of work is such that teams of personnel are not required;

(ii) no additional professional support is required;

(iii) the experience and qualifications of the individual are the paramount requirement.

(b) individual consultants may not be required to submit proposals, and may be selected on the basis of the evaluation of their curriculum vitae. Interviews may be set up for selection under this method

73. Request for Expression of Interest

(1) Request for Expression of Interest shall be advertised or announced in accordance with the provisions of Rule 17 and 18 above;

(2) Request for Expression of Interest shall contain the following information:

(a) name and address of procuring agency;

(b) appropriate description of the assignment providing scope of the intellectual and professional services required;

(c) deadline and place of the submission of Request for Expression of Interests;

(d) criteria for short listing; and

(e) any other information that the procuring agency may deem appropriate to disseminate at this stage.

74. Criteria for Short-listing of Consultants

(1) Procuring agency shall short list the applicants according to a pre-determined criteria mentioned in the Request for Expression of Interest;

(2) The procuring agency while engaged in short listing of consultants shall take into consideration the following factors:

(a) qualification;

(b) experience;

(c) financial capability; and

(d) any other factor that a procuring agency may deem relevant not inconsistent with these Rules.

75. Request for Proposals

(1) The procuring agency shall use Request for Proposal for seeking proposals from the shortlisted consultants, which shall include the following:

(a) Letter of Invitation - It shall mention the name and address of the procuring agency and shall also state the intention of the procuring agency to enter into a contract for provision of consulting services and contain names of all the short listed firms;

(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 - It shall define the objectives, goals and scope of the assignment unambiguously and list the deliverables, services and surveys necessary to carry out the assignment and expected outputs. Terms of Reference are to be read along with the conditions mentioned in the Form of Contract;

(d) Form of Contract - Form of contract is a draft contract agreement which includes all general and special conditions of contract;

(e) Evaluation Criteria - Except as otherwise provided, the evaluation of proposals shall be carried out giving due consideration to quality and cost;

(f) Types of Contract - The procuring agency may use one of the following types of contract:

(i) lump sum contract shall be used mainly for assignments in which the contents, duration of the services and the required output are unambiguously defined;

(ii) time based contract shall be used when it is difficult to define the scope and the length of services;

(iii) hourly or daily rates contract shall be used for small projects, especially when the assignment is for less than a month; and

(iv) any other contract, based on combination of the above types of contracts, including out of pocket expenses, where required.

(g) Special provisions - The procuring agency may specify any other requirement related to the assignment or contract, where required.

(2) The procuring agency shall invite the interested consultants to submit their technical and financial proposals in separate sealed envelopes. The procuring agency shall give deadline for submission of proposals. Consultants shall be given adequate time in which to prepare their proposals which shall not be less than 15 days for National Competitive Bidding and 45 days for International Competitive Bidding.

76. Criteria for Evaluation of Quality of Consulting Services – Evaluation criteria shall include, but shall not be limited to the following;

(1) Specialization: Consultants' specialized skills and access to particular technologies related to the assignment;

(2) Experience: Consultants' experience and past performance on similar contracts or assignments and in similar geographical conditions;

(3) Financial Capability: Financial capability of the consulting firms may be evaluated with a view to ensuring that they can complete the assigned task in a timely manner;

(4) Understanding of the Assignment: Consultant's understanding of the assignment is a very important consideration for evaluation;

(5) Proposed Methodology: Methodology proposed by the consultants shall be evaluated for its innovativeness and soundness;

(6) Quality Management: Availability of a well-established Quality Management system may be taken into account for large and complex assignments.

77. Association between Consultants

(1) An association of consultants may take either the form of a consortium or a sub-consultancy.

(2) Under a consortium arrangement only one entity, either through the lead consultant or by forming a legal juridical person, shall be responsible to the Government for execution of the entire assignment

(3) Under sub-consultancy, the main consultant may engage another consultant for performing part of an assignment, only if expressly provided in the contract agreement and expressly agreed to by the procuring agency. The main consultant shall, however, bear all responsibility for quality of the output and in all other respects as provided in the main contract.

78. Intellectual Property Rights

(1) All documents, reports, designs, research work and all deliverables prepared by the consultant shall become and remain the property of the procuring agency;

(2) Any restrictions on the future use of these documents and software by the consultant shall be specified in the conditions of the contract.

79. Extent of Contract Negotiation – Procuring agency may negotiate with the highest ranked bidder regarding methodology, work plan, staffing and special conditions of the contract. 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.

80. Professional Liability of Consultants

(1) The consultant selected and awarded a contract shall be liable for consequence of omissions or commissions on his or their part. The extent of liability of consultant shall be incorporated in the contract, and in no case, shall be less than the remuneration, excluding out of pocket expenses, nor shall the liability exceed twice the amount of remunerations;

(2) The procuring agency may demand insurance on part of the consultant to cover its liability as stated above, and necessary costs shall be borne by the consultant;

(3) The consultant shall be liable for all losses or damages suffered by the procuring agency on account of any misconduct by the consultant in performing the consulting services.

PART IV – PUBLIC PRIVATE PARTNERSHIP PROJECTS

81. Public Private Partnership Projects

(1) The rules under this part shall be applicable for procurement of goods, works and services through Public Private Partnership;

(2) The rules for procurement of goods, works and services in Parts II and III shall *mutatis mutandis* apply to the projects in which the design, financing and operations and maintenance will be undertaken under any of the following mode of procurement;

(a) Service Contract

(b) Management Contract

(c) Lease Contract

(d) Build, Operate and Transfer

(e) Build, Own and Operate

(f) Design, Build, Finance and Operate and Transfer

(g) Build, Own, Operate, Transfer

(h) Build, Lease and Transfer

(i) Build and Transfer

(j) Rehabilitate, Operate and Transfer

(k) any combination or variation of the above modes or any other arrangement under PPP mode approved by the Authority.

(3) The competent authority to approve PPP Projects and related processes for all sectors shall rest with the Public Private Partnership Policy Board;

(4) In case of any conflict in provisions or their interpretation within the rules, for PPP projects rules under this part shall take precedence over rules in other parts.

82. Procurement Process under Public Private Partnership

(1) Some or all the functions and responsibilities of procurement planning and execution may be performed by the professional transaction advisers and consultants subject to approval by the Public Private Partnership Policy Board;

(2) The Government shall appoint a committee for each Public Private Partnership project for technical and financial evaluation for evaluating the project. The terms of reference of each such committee shall be approved by the Government;

(3) Except otherwise provided in these rules all the Public Private Partnership contracts and concessions shall be granted through national or international open competitive bidding, as the case may be;

(4) The procuring agency may levy a reasonable fee for submitting requests for proposals. Such fee shall not exceed Rs. 100,000/-;

(5) Bidding documents shall be prepared according to Rule 21 and shall also include the following;

(a) minimum design and performance standards and specifications, land and economic parameters;

(b) draft concession or management contract;

(c) other documents as may be deemed necessary by the procuring agency concerned;

(6) The instructions to bidders shall be unambiguous, comprehensive and fair to all bidders and shall, as far as necessary and practicable, include but not be limited to the following information;

(a) general description and objectives of the project;

(b) bid submission procedures and requirements, which shall include information on the manner of bid submission, the number of copies of bid proposal to be submitted, where the bids are to be submitted, the deadline for the submission of bids and permissible mode of transmission of bid proposals;

(c) Government undertaking such incentives to be provided, subsidies debt financing, if any, and equity by government or other government guarantees;

(d) bid security and bid validity period;

(e) milestone bonding;

(f) method and criteria, including the minimum amount and form of equity, for the evaluation of the bids;

(g) formulas and indices to be used in the adjustments of tolls, fees, rentals, royalties and charges, where applicable;

(h) requirements of concerned regulatory bodies, if any;

(i) monetary rules and regulation governing foreign exchange remittances;

(j) revenue sharing arrangements;

(k) expected commissioning date.

(7) Minimum design and performance standards or specifications, including applicable environmental standards shall be clearly defined and shall refer more to the desired quantity and quality of the outputs of the facility and shall state that non-conformity with any of these minimum requirements shall render the bids as non-responsive. Likewise, the following economic and financial parameters, among others, shall be prescribed:

(a) discount rate and foreign exchange rate as prescribed by the government, where applicable;

(b) maximum period of project construction;

(c) fixed term or variable term for project operation and collection of tolls, fees, rentals and charges authorized or approved by the government;

(d) formula and price indices to be used for adjustments in tolls, fees, rentals and charges, in the case of Build Operate Transfer, Build Operate Own and other variations thereof authorized or approved by the government;

(e) other financial features embedded in the Public Private Partnership project to enhance Value for Money.

83. Negotiations

(1) Notwithstanding the provisions of Rule 52, negotiations may be permissible after the financial bids have been opened. In case the procuring agency has valid reasons, which must be recorded in writing, that the financial offers are not providing best value for money or need changes, the procuring agency may invite sealed revised financial bids from all qualified bidders or through open bidding. The procuring agency shall keep complete minutes of the negotiation process;

(2) Direct negotiations shall be resorted to when there is only one complying bidder left as defined hereunder:

(a) If, in response to advertisement, only one interested bidder responds for prequalification, and it meets the pre-qualification criteria;

(b) If after advertisement, more than one interested bidders respond for pre-qualification, if any but only one of them meets the prequalification criteria;

(c) After pre-qualification, if any, more than one interested bidders respond, and only one of them submits a bid, which is found by procuring agency to be complying;

(d) After pre-qualification, if any, more than one interested bidders submits the bid, but only one is found by the procuring agency to be complying.

84. Bid Evaluation –

The best evaluated bid shall be determined on the basis of the following criteria;

(1) Lowest bid in terms of user fees if the concession period is fixed.

(2) Highest return or profit for the government if the concession period is fixed and the user fees is the same or lower than other bidder.

(3) Shortest concession period if the user fee is fixed.

(4) Lowest Net Present Value of return to the bidder if user fee, concession period and subsidy element is same as those of other bidders, if government equity is not involved.

(5) Lowest amount of subsidy if the other considerations are almost same.

(6) Any other factor deemed relevant to the particular project by the procuring agency.

85. Award of Contract

(1) Notwithstanding anything contained in these rules, award of contract under Public Private Partnership shall be based on the criteria of evaluation prepared by the procuring agency, and published along with the Request for Proposal. Subsequently, if procuring agency deems it necessary to change the evaluation criteria after the Request for Proposal has been issued, it shall issue fresh Request for Proposal to afford equal opportunity to all the interested bidders;

(2) In so far as applicable, the same rules provided for the evaluation of the technical and financial aspects of bid proposals in Part II shall be applied in the evaluation of single bid;

(3) The procuring agency concerned shall have the right to cancel bidding process, as provided in Rule 25.

86. Unsolicited Proposal

(1) To promote and invigorate innovation the government may receive unsolicited proposals for Public Private Partnership investment from any source;

(2) The concerned procuring agency shall get the proposal reviewed by their respective technical committee to determine whether the project for which the proposal has been submitted is an appropriate project for implementation under Public Private Partnership mode. Such proposal, if found feasible for Public Private Partnership mode, shall be submitted to the Public Private Partnership Unit, Finance Department, Government of Sindh for approval of concept. The concerned procuring agency shall carry out further process in collaboration with the Public Private Partnership Unit;

(3) The initiator of the unsolicited proposal shall be exempt from the prequalification process;

(4) Procuring agencies shall ensure competitiveness through advertising the proposed project for open bidding without disclosing the name of the initiator of unsolicited proposal. The initiator will be given five percent additional weightage on the combined secured score, technical and financial, in evaluation. If there is no other bid submitted in response to the competitive bidding, the procuring agency may award the contract to the initiator under these rules.

87. Power to Frame Procedures –

Public Private Partnership Unit, Finance Department, Government of Sindh shall be empowered to devise guidelines and procedures for effective, efficient and transparent procurement process for Public Private Partnership projects, subject to concurrence by the Authority.

88. Removal of Difficulties –

To remove the difficulties with respect to any procurement related issues, not expressly covered in these rules, the procuring agencies or the Unit shall refer the matter to the Authority for resolution. The Authority shall co-opt a representative of Public Private Partnership Unit in a committee, formed to resolves such issues.

PART V – GENERAL

89. Integrity Pact –

Procurements exceeding Rs. 10 million for goods and works, and Rs. 2.5 million for services shall be subject to an integrity pact, as specified by regulations, between the procuring agency and the suppliers or contractors or consultants.

90. Overriding Effect –

Provisions of these rules shall have overriding effect notwithstanding anything to the contrary contained in any other Rules, Regulations, Manuals, Instructions or Orders issued by the Government from time to time concerning public procurements.

91. Repeal and Savings –

Public Procurement Rules, 2004 as adopted by the Government of Sindh shall stand repealed on coming into force of these rules. However, procurement processes already initiated shall be completed according to the statutory framework applicable at the time of initiation of such procurements.

Appendix-A[XXX][41]

[41] *Omitted vide SGA&CD Notification No. SORI(SGA&CD)2-30/2010 dated 8th October, 2013*

Appendix 2: 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 the Federal 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 writingin inedible ink in a conspicuous manner on the label of the innermost container of adrug 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 per tablets, 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 internaluse, except a drug contained in a strip or foil or blister or collapsible tube, shall, inaddition to the particulars required to be given under rule 3, bear in a conspicuousmanner:

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, inaddition to the particulars required to be given under rule 3, bear in a conspicuousmanner:

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 fordistribution to the medical profession as free sample shall, in addition to the particularsrequired to be given under these rules, bear the words "Physician's sample: Not forsale" 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 anampoule of a capacity of not more than three milliliters or in a collapsible tube, it shallbe 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 drugintended for the supply to any Government agency, including an autonomous body or asemi-Government Agency

shall, while complying with the other labeling requirementsof these rules, bear the words or mark reading "Government Supply" or such otherwords 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 useshall bear in a conspicuous manner, preferably in red ink the words for veterinary useonly.

9. Outer transparent wrapper not to require labeling: Nothing in these rules shall bedeemed to require the labeling of any transport cover, wrapper, case or other coveringused 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 everywrapper enclosing a surgical ligature or suture, other than a ligature or suture certifiedto be sterile and fit for surgical use without further sterilization, shall bear a label onwhich 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 bodyunless properly sterilized".

11. Use of letter to indicate specifications: If a drug is included in the recent edition ofany publication specified in the rules, the name of relevant publication in conventionalabbreviations (B.P., U.S.P., etc.) shall be printed in indelible ink, on the label to indicatethat 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 containersintended 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 fortreatment, whether after or without dilution and is supplied by a person licensed to selldrugs 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.

Appendix3: Standard Bidding Documents for Procurement of Contraceptives through

Overview of Standard Bidding Documents

The standard bidding document package will usually consist of the following documents:

- Instructions to Bidder
- Bid Data Sheet (BDS)
- General Conditions of Contract (GCC)
- Special Conditions of Contract
- Technical Specifications
- Schedule of Requirements
- Special forms, that 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 BDS 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 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 BDS 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 GCC 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 purchaser, as specified in the Bid Data Sheet (BDS) and in the Special Conditions of Contract (SCC), invites bids for the supply of contraceptives (as specified in the BDS described in the Schedule of Requirements. The name and identification number of the Contract is provided in the BDS and in the SCC.

1.2 Throughout these bidding documents, the term *writing* means any type written,or printed communication, including email, telex, cable, and facsimile transmission, and *day* means calendar day. Singular also means plural.

2. Fraud and Corruption

2.1 It is the Government of Sindh's (Rule 2(1) (q) of SPPR, 2010) 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:

(a)

(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

(a) 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; or

(b) the purchaser will reject a proposal for award if it determines that the bidder recommended for award has, directly or through an agent, engaged in corrupt, fraudulent, collusive, coercive or obstructive practices in competing for the contract in question;

(c) the purchaser 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 an agent, engaged in corrupt, fraudulent,

collusive, coercive or obstructive practices in competing for, or in executing, the contract; and

(d) the purchaser 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 purchaser 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 purchaser.

2.2 Furthermore, bidders shall be aware of the provision stated in sub-clauses 5.4 and 23.1 (d) of the GCC.

3. Eligibility

3.1 Except as provided in ITB sub-clauses 3.2 and 3.3, this bidding process is open to qualified (prequalified or not) firms from any country;

3.2 Firms of a country may be excluded from bidding if:

(a) as a matter of law or official regulation, the GOP prohibits commercial relations with that country;

(b) government-owned enterprises in Pakistan may participate only if they can establish that they

(i) are legally and financially autonomous and

(ii) operateunder commercial law.

3.3 A firm declared ineligible by the Government of Sindh shall be ineligible to bid for a contract during the period of time determined by the Government of Sindh.

3.4 A firm that has been determined to be ineligible by the GOP in relation to the *Guidelines on Preventing and Combating Fraud and Corruption* shall not be eligible to be awarded a contract.

4. Documents Establishing Conformity to Bidding Documents

4.1 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:

(a) a detailed description of the essential technical and performance characteristics of the contraceptives;

(b) an item-by-item commentary on the purchaser'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;

(c) any other procurement-specific documentation requirement as stated in the BDS.

4.2 Unless the BDS stipulates otherwise, the contraceptives to be supplied under the contract shall be registered with the Drug Regulatory Authority of Pakistan, as required. A bidder who has already registered its contraceptives by the time of bidding should submit a copy of the registration certificate with its bid.

4.2.1 If the contraceptives of the successful bidder have not been registered in the purchaser's country at the time of contract signing, then the contract shall become effective upon such

date as the certificate of registration is obtained.

4.3 For purposes of the commentary to be furnished pursuant to ITB clause 4.1 (b) above, the bidder shall note that standards as well as references to brand names designated by the purchaser in its technical specifications are intended to be descriptive only and not restrictive. The bidder may substitute alternative standards, brand names, and/or catalogue numbers in its bid, provided that it demonstrates to the purchaser's satisfaction that the substitutions ensure substantial equivalence to those designated in the technical specifications.

5. Qualifications of the Bidder

5.1 The bidder shall provide documentary evidence to establish to the purchaser's satisfaction that:

(a) the bidder has the financial, technical, and production capability necessary to perform the contract, meets the qualification criteria specified in the BDS, and has a successful performance history in accordance with criteria specified in the BDS. If a prequalification process has been undertaken for the contract, the bidder shall, as part of its bid, update any information submitted with its application for prequalification.

(b) in the case of a bidder offering to supply contraceptives, identified in the BDS, that the bidder did not manufacture or otherwise produce, the bidder has been duly authorized by the manufacturer or producer of such contraceptives to supply the contraceptives in the purchaser's country;

(c) in the case of a bidder who is not doing business within the purchaser's country (or for other reasons will not itself carry out service/maintenance obligations), the bidder is or will be (if awarded the contract) represented by a local service/ maintenance provider in the purchaser's country equipped and able to carry out the bidder's warranty obligations prescribed in the Conditions of Contract and/ or Technical Specifications; and

(d) the bidder meets the qualification criteria listed in the BDS (see additional clauses of BDS for pharmaceuticals and vaccines).

6. One Bid per Bidder

6.1 A firm shall submit only one bid either individually or as a partner of a joint venture (other than in cases of alternatives pursuant to ITB clause 18). A firm that submits either individually or, as a member of a joint venture, more than one bid will cause all the proposals with the firm's participation to be disqualified.

7. Cost of Bidding

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

B. Bidding Documents

8. Content of Bidding Documents

8.1 The bidding documents are those stated below and should be read, in conjunction with any addendum issued in accordance with ITB clause 10.

Section I. Instructions to Bidders (ITB)

Section II. Bid Data Sheet (BDS)

Section III Eligibility

Section IV. General Conditions of Contract (GCC)

Section V. Special Conditions of Contract (SCC)

Section VI. Schedule of Requirements

Section VII. Technical Specifications

Section VIII. Sample Forms (including Contract Agreement)

8.2 The IFB does not form part of the bidding documents and is included as a reference only. In case of discrepancies between the IFB and the bidding documents listed in 8.1 above, said bidding documents will take precedence.

9. Clarification of Bidding Documents

9.1 A prospective bidder requiring any clarification of the bidding documents shall contact the purchaser in writing or by cable (for these ITB, the term *cable* is deemed to include electronic mail, telex, or facsimile) at the purchaser's address indicated in the BDS. The purchaser will respond in writing to any request for clarification received no later than fourteen (14) calendar days prior to the deadline of submission of bids. Copies of the purchaser's response shall be sent to all prospective bidders who have purchased the bidding documents, including a description of the inquiry but without identifying its source.

10. Amendment of Bidding Documents

10.1 At any time prior to the deadline for submission of bids, the purchaser may amend the bidding documents by issuing an addenda.

10.2 Any addendum thus issued shall be part of the bidding documents pursuant to ITB Sub-clause 8.1 and shall be communicated in writing to all purchasers of the bidding documents and will be binding on them. Bidders are required to immediately acknowledge receipt of any such amendment, and it will be assumed that the information contained in the amendment will have been taken into account by the bidder in its bid.

10.3 To give prospective bidders reasonable time in which to take the amendment into account in preparing their bids, the purchaser shall extend, at its discretion, the deadline for submission of bids, in which case, the purchaser will notify all bidders by cable confirmed in writing of the extended deadline.

C. Preparation of Bids (Single-stage–two-envelope procedure)

11. Language of Bid

11.1 The bid, as well as all correspondence and documents relating to the bid exchanged by the bidder and the purchaser, shall be written in the language specified in the BDS. Supporting documents and printed literature furnished by the bidder may be in another language provided they are accompanied by an accurate translation of the relevant passages in the language specified, in which case, for purposes of interpretation of the bid, the translation shall govern.

12. Documents Constituting the Bid

12.1 The bid submitted by the bidder shall comprise the following:

(a) duly filled-in Form of Bid and Price Schedule, in accordance with the forms indicated in section VIII;

(b) original form of bid security, in accordance with the provisions of ITB sub-clause 19 (Bid Security);

(c) alternative offers, at the bidder's option, when permitted;

(d) written power of attorney authorizing the signatory of the bid to commit the bidder;

(e) documentary evidence establishing to the purchaser's satisfaction, and in accordance with ITB clause 5 that the bidder is qualified to perform the contract if its bid is accepted. In the case where prequalification of bidders has been undertaken, and pursuant to ITB paragraph 5.1(a), the bidder must provide evidence on any changes in the information submitted as the basis for prequalification, or if there has been no change at all in said information, a statement to this effect;

(f) any other documentation as requested in the BDS.

13. Bid Form

13.1 The bidder shall complete the bid form and the appropriate price schedule furnished in the bidding documents, indicating the contraceptives to be supplied, a brief description of the contraceptives, their country of origin, quantity and prices.

13.2 For the purpose of granting a margin of domestic preference, bids will be classified in one of three groups, as follows:

(a) Group A: Bids offering contraceptives manufactured in the purchaser's country, for which (i) labor, raw materials, and components from within the purchaser's country account for more than thirty (30) percent of the Ex Works price; and (ii) the production facility in which they will be produced or manufactured has been engaged in producing or manufacturing such contraceptives at least since the date of bid submission.

(b) Group B: All other bids offering contraceptives from within the country of the purchaser.

(c) Group C: Bids offering contraceptives of foreign origin already imported or to be imported by the purchaser directly or through the supplier's local agent.

13.3 To facilitate this classification by the purchaser, the bidder shall complete whichever version of the Price Schedule furnished in the bidding documents is appropriate, provided the completion of an incorrect version of the price schedule by the bidder will not result in rejection of its bid, but merely in the purchaser's reclassification of the bid into its appropriate bid group.

14. Bid Prices

14.1 Prices shall 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 purchaser. This shall not in any way limit the purchaser's right to contract on any of the terms offered.

14.2 Prices shall be entered in the following manner:

(a) For contraceptives manufactured in the purchaser's country:

(i) the price of the contraceptives quoted Ex Works (EXW), (price fixation at

manufacturer's premises), including all customs duties and sales and other taxes already paid or payable on the components and raw material used in the manufacture or assembly of the contraceptives;

(ii) any purchaser's country sales tax and other taxes which will be payable on the contraceptives if the contract is awarded to the bidder; and

(iii) the price for inland transportation, insurance and other local services required to convey the contraceptives to their final destination specified in the BDS.

(b) For contraceptives manufactured outside the purchaser's country, to be imported:

(i) the price of the contraceptives, quoted CIP named place of destination, in the purchaser's country, or CIF named port of destination, as specified in the BDS;

(ii) the price for inland transportation, insurance and other local services required to convey the contraceptives from the named place of destination to their final destination specified in the BDS;

(iii) in addition to the CIP prices specified in (b)(i) above, the price of the contraceptives to be imported may be quoted FCA (named place of destination) or CPT (named place of destination), if so specified in the BDS;

(c) For contraceptives manufactured outside the purchaser's country, already imported:

(For previously imported contraceptives, the quoted CIP price shall be distinguishable from the original import value of these contraceptives declared to customs and shall include any rebate or mark-up of the local agent or representative and all local costs except import duties and taxes, which have been and/or have to be paid by the purchaser. For clarity, the bidders are asked to quote the price including import duties, and additionally to provide the import duties and the CIP price which is the difference of those values.)

(i) the price of the contraceptives, including the original import value of the contraceptives; plus any mark-up (or rebate); plus any other related local cost, and custom duties and other import taxes already paid or to be paid on the contraceptives already imported.

(ii) the custom duties and other import taxes already paid (need to be supported with documentary evidence) or to be paid on the contraceptives already imported;

(iii) the price of the contraceptives, quoted CIP named place of destination, in the purchaser's country obtained as the difference between (i) and (ii) above;

(iv) any purchaser's country sales and other taxes, which will be payable on the contraceptives if the contract is awarded to the bidder; and

(v) the price for inland transportation, insurance and other local services required to convey the contraceptives from the named place of destination to their final destination specified in the Bid Data Sheet.

(d) for related services, other than inland transportation and other services required to convey the contraceptives to their final destination, whenever such related services are specified in the Schedule of Requirements:

(i) the price of each item comprising the related services (inclusive of any applicable

taxes).

14.3 The terms EXW, CIF, CIP, etc., shall be governed by the rules prescribed in the current edition of Incoterms published by the ICC, Paris.

14.4 The bidder's separation of price components in accordance with ITB clause 14.2 above will be solely for the purpose of facilitating the comparison of bids by the purchaser and will not in any way limit the purchaser's right to contract on any of the terms offered.

14.5 Unless otherwise specified in the BDS, 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 ITB clause 27. If, however, in accordance with the BDS, prices quoted by the bidder shall be subject to adjustment during the performance of the Contract, a bid submitted with a fixed price quotation will not be rejected, but the price will not be adjusted.

14.6 Pursuant to sub-clause 14.1 above, and if so indicated in the BDS, bids are being invited for one or more items, or for individual Contracts (lots) each comprising at least eighty percent (80%) of the total number of items required under the lot. In both cases, 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.

15. Currencies of Bid

15.1 Prices shall be quoted in the following currencies:

(a) The bidder may express the bid price of the contraceptives to be supplied from outside the purchaser's Country entirely in the currency or currencies of Bank member countries. If the bidder wishes to be paid in a combination of different currencies, it must quote its price accordingly, but no more than three foreign currencies may be used.

(b) Unless otherwise specified in the BDS, the bidder shall express its prices for such contraceptives to be supplied from within the purchaser's country in the currency of the country of the borrower.

16. Period of Validity of Bids

16.1 Bids shall remain valid for the period stipulated in the BDS after the date of bid submission specified in ITB clause 21. A bid valid for a shorter period shall be rejected by the purchaser as nonresponsive.

16.2 In exceptional circumstances, prior to expiry of the original bid validity period, the purchaser may request that the bidders 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 forfeiting its bid security. Except as provided in ITB clause 16.3, a bidder agreeing to the request will not be required or permitted to modify its bid, but will be required to extend the validity of its bid security for the period of the extension.

16.3 In the case of fixed price contracts, if the award is delayed by a period exceeding fifty-six (56) days beyond the expiry of the first bid validity extension, the contract price will be increased by a factor that reflects changes in the cost of inputs specified in the request for second and

subsequent extensions.

17. Bid Security

17.1 If required, in the BDS, the bidder shall furnish, as part of its bid, a bid security as specified in the BDS, or a Bid Securing Declaration. The amount of the bid security shall be as stipulated in the BDS in the currency of the purchaser's country, or the equivalent amount in a freely convertible currency.

17.2 The bid security shall remain valid for a period of 28 days beyond the validity period for the bid, and beyond any extension subsequently requested under sub-clause 16.2.

17.3 The bid security shall, at the bidder's option, be in the form of either a L/C or a bank guarantee from a reputable banking institution, or a bond issued by a surety selected by the bidder and located in any country. If the institution issuing the bond is located outside the purchaser's country, it shall have a correspondent financial institution located in the purchaser's country to make it enforceable. The format of the bank guarantee/bond shall be in accordance with the forms included in the bidding documents; other formats may be permitted, subject to the prior approval of the purchaser.

17.4 Any bid not accompanied by an acceptable bid security shall be rejected by the purchaser as non-responsive. The bid security of a joint venture must be in the name of the joint venture submitting the bid.

17.5 The bid securities of unsuccessful bidders will be returned as promptly as possible.

17.6 The bid security of the successful bidder will be returned when the bidder has signed the Contract and furnished the required performance security.

17.7 The bid security may be forfeited:

(a) if the bidder withdraws its bid, except as provided in ITB sub-clauses 16.2 and 23.3; or

(b) in the case of a successful bidder, if the bidder fails within the specified time limit to:

(i) sign the contract; or

(ii) furnish the required performance security.

17.8 If a bid security is not required in the BDS, and

(a) if a bidder withdraws its bid during the period of bid validity specified by the bidder on the Letter of Bid Form, except as provided in ITB 16.2, or

(b) if the successful bidder fails to sign the Contract in accordance with ITB 37, or furnish a performance security in accordance with ITB 38, the borrower may, if provided for in the BDS, declare the bidder disqualified to be awarded a contract by the Employer for a period of time as stated in the BDS.

18. Alternative Bids by Bidders

18.1 Unless specified in the BDS, alternative bids shall not be accepted.

19. Format and Signing of Bid

19.1 The bidder shall prepare an original and the number of copies/sets of the bid indicated in the BDS, 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.

19.2 The original and all copies of the bid, each consisting of the documents listed in ITB sub-

clause 12.1, shall be typed or written in indelible ink and shall be signed by the bidder or a person or persons duly authorized to bind the bidder to the Contract. The later authorization shall be indicated by written power of attorney, which pursuant to ITB sub-clause 12.1 (d) shall accompany the bid.

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

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

D. Submission of Bids

20. Sealing and Marking of Bids

20.1 Bidders may always submit their bids by mail or by hand.

(a) The bidder shall enclose the original and each copy of the bid, including alternative bids if permitted in accordance with ITB clause 18, 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.

20.2 The inner and outer envelopes shall:

(a) bear the name and address of the bidder;

(b) be addressed to the purchaser at the address given in the BDS;

(c) Clearly mark inner envelopes separately as Financial and Technical Bids

(d) bear the specific identification of this bidding process indicated in the BDS, the IFB title and number indicated in the BDS; and

(e) bear a statement "DO NOT OPEN BEFORE (date and time)" to be completed with the time and date specified in the BDS relating to ITB sub-clause 21.1.

20.3 If the outer envelope is not sealed and marked as required by ITB sub-clause 20.2 the purchaser will assume no responsibility for the misplacement or premature opening of the bid.

21. Deadline for Submission of Bids

21.1 Bids must be received by the purchaser at the address specified in the BDS relating to ITB sub-clause 20.2 (b) no later than the time and date specified in the BDS.

21.2 The purchaser may, at its discretion, extend the deadline for the submission of bids by amending the bidding documents in accordance with ITB sub-clause 10.3, in which case all rights and obligations of the purchaser and bidders previously subject to the deadline will thereafter be subject to the deadline as extended.

22. Late Bids

22.1 Any bid received by the purchaser after the deadline for submission of bids prescribed by the purchaser in the BDS pursuant to ITB clause 21 will be rejected and returned unopened to the bidder.

23. Modification and Withdrawal of Bids

23.1 The bidder may modify or withdraw its bid after submission, provided that written notice of the modification, or withdrawal of the bids duly signed by an authorized representative, is received by the purchaser prior to the deadline prescribed for submission of bids.

23.2 The bidder's modification shall be prepared, sealed, marked and dispatched as follows:

(a) The bidder shall provide an original and the number of copies specified in the BDS of any modifications to its bid, clearly identified as such, in two inner envelopes duly marked "BID MODIFICATION-ORIGINAL" and "BID MODIFICATION-COPIES". The inner envelopes shall be sealed in an outer envelope which shall be duly marked "BID MODIFICATION".

(b) Other provisions concerning the marking and dispatch of bid modifications shall be in accordance with ITB sub-clauses 22.2 and 22.3.

23.3 A bidder wishing to withdraw its bid shall notify the purchaser in writing prior to the deadline prescribed for bid submission. A withdrawal notice shall be received prior to the deadline for submission of bids. The notice of withdrawal shall:

(a) be addressed to the purchaser at the address named in the BDS,

(b) bear the specific identification of the bidding process (Contract name), the IFB title and IFB number, and the words "BID WITHDRAWAL NOTICE," and

(c) be accompanied by a written power of attorney authorizing the signatory of the withdrawal notice to withdraw the bid.

23.4 Bids requested to be withdrawn in accordance with ITB sub-clause 23.3, shall be returned unopened to the bidders.

23.5 No bid may be withdrawn in the interval between the bid submission deadline and the expiration of the bid validity period specified in ITB clause 16. Withdrawal of a bid during this interval may result in the forfeiture of the bidder's bid security, pursuant to ITB Sub-clause 17.7.

E. Opening and Evaluation of Bids

24. Bid Opening

24.1The purchaser will open all bids, including withdrawal notices and modifications, in public, in the presence of bidders' representatives who choose to attend at the time, on the date and at the place specified in the BDS. Any specific electronic bid opening procedures required if electronic bidding is permitted in accordance with ITB clause 20.1 shall be as specified in the BDS. Bidders' representatives shall sign a register as proof of their attendance.

24.2 Envelopes marked "WITHDRAWAL" shall be read out and the envelope with the corresponding bid shall not be opened but returned to the bidder. No bid withdrawal notice shall be permitted unless the corresponding withdrawal notice is read out at bid opening. Envelopes marked "MODIFICATION" shall be read out and opened with the corresponding bid.

24.3 Bids shall be opened one at a time, reading out: the name of the bidder and whether there is a modification; the bid price of each item or lot, as the case may be, including discounts and alternative offers, if allowed in the BDS; the presence or absence of a bid security, if required; the presence or absence of requisite powers of attorney; and any other such details as the

purchaser may consider appropriate. No bid shall be rejected at bid opening except for late bids pursuant to sub-clause 22.1.

24.4 Bids (and modifications sent pursuant to ITB sub-clause 23.2) that are not opened and read out at bid opening shall not be considered further for evaluation, irrespective of the circumstances.

24.5 The purchaser will prepare minutes of the bid opening at the end of the opening session, including, as a minimum: the name of the bidder and whether there was a withdrawal or modification; the bid price; including any discounts or alternatives offered if permitted in the BDS; the presence or absence of a bid security; the presence or absence of requisite powers of attorney.

24.6 The bidder's representatives who are present shall be requested to sign the minutes. The omission of a bidder's signature on the minutes shall not invalidate the content and effect of the minutes. The minutes should be distributed to all bidders who request them.

25. Clarification of Bids

25.1 During evaluation of the bids, the purchaser may, at its discretion, ask the bidder for a clarification of its bid. The request for clarification and the response shall be in writing, and no change in the prices or substance of the bid shall be sought, offered or permitted, except to correct arithmetic errors identified by the purchaser in the evaluation of the bids, in accordance with 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 to all bidders.

26.2 Any effort by the bidder to influence the purchaser in the purchaser's bid evaluation, bid comparison or contract award decisions may result in the rejection of the bidder's bid.

26.3 From the time of bid opening to the time of Contract award, if any bidder wishes to contact the purchaser on any matter related to its bid, it should do so in writing.

27. Examination of Bids and Determination of Responsiveness

27.1 The purchaser will examine the bids to determine whether they are complete, whether any computational errors have been made, whether required sureties have been furnished, whether the documents have been properly signed and whether the bids are generally in order. In the case where a pre-qualification process has been undertaken for the Contract(s) for which these Bidding Documents have been issued, the purchaser will ensure that each bid is from a prequalified bidder.

27.2 The purchaser may waive any minor informality, nonconformity or irregularity in a bid that does not 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, pursuant to ITB clause 30, the purchaser will 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, conditionalities, or reservations. A material deviation, exception, objection, conditionality, or reservation is one: (i) that limits in any substantial way the scope, quality or performance of the contraceptives and related Services; (ii) that limits, in any substantial way that is inconsistent with the Bidding Documents, the purchaser's rights or the successful bidder's obligations under the Contract; and (iii) that 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 will be rejected by the purchaser and may not subsequently be made responsive by the bidder by correction of the nonconformity. The purchaser's determination of a bid's responsiveness is to be based on the contents of the bid itself.

28. Correction of Errors

28.1 Arithmetical errors will be rectified as follows. If there is a discrepancy between the unit price and the total price that is obtained by multiplying the unit price and quantity, the unit or subtotal price shall prevail. If there is a discrepancy between subtotals and the total price, the total price shall be corrected. If there is a discrepancy between words and figures, the amount in words will prevail. If a bidder does not accept the correction of errors, its bid will be rejected.

29. Conversion to Single Currency

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

(a) the currency of the purchaser's country at the selling exchange rate established for similar transactions by the Central Bank or a commercial bank in the purchaser's country.

or

(b) a currency widely used in international trade, such as U.S. dollars, at the selling rate of exchange published in the international press for the amount payable in foreign currency; and at the selling exchange rate established for similar transactions by the Central Bank in the purchaser's country for the amount payable in the currency of the purchaser's country.

29.2 The currency selected for converting bid prices to a common base for the purpose of evaluation, along with the source and date of the exchange rate, are specified in the BDS.

30. Evaluation and Comparison of Bids

30.1 The purchaser will evaluate and compare the bids that have been determined to be substantially responsive, pursuant to ITB clause 27.

30.2 The purchaser's evaluation of a bid will exclude and not take into account:

(a) in the case of contraceptives manufactured in the purchaser's country or contraceptives of foreign origin already located in the purchaser's country, sales and other similar taxes that will be payable on the contraceptives if a contract is awarded to the bidder;

(b) in the case of contraceptives of foreign origin already imported and to be imported from abroad, customs duties and other similar import taxes paid or payable on the contraceptives if the contract is awarded to the bidder; and

(c) any allowance for price adjustment during the period of execution of the Contract, if

provided in the bid.

30.3 The comparison shall be between the EXW price of the contraceptives offered from within the purchaser's country plus local transportation, such price to include all costs, as well as duties and taxes paid or payable on components and raw material incorporated or to be incorporated in the contraceptives, and the CIF named port of destination (or CIP border point, or CIP named place of destination) price of the contraceptives offered from outside the purchaser's country, plus local transportation.

30.4 The purchaser's evaluation of a bid will take into account, in addition to the bid price quoted in accordance with ITB sub-clause 16.2, one or more of the following factors as specified in the BDS, and quantified in ITB sub-clause 32.5:

(a) delivery schedule offered in the bid;

(b) deviations in payment schedule from that specified in the Special Conditions of Contract;

(c) other specific criteria indicated in the BDS and/or in the Technical Specifications.

30.5 For factors retained in the BDS pursuant to ITB sub-clause 30.4, one or more of the following quantification methods will be applied, as detailed in the BDS:

(a) Delivery schedule.

(i) The purchaser requires that the contraceptives under these Bidding Documents shall be delivered (shipped) at the time specified in the Schedule of Requirements. The estimated time of arrival of the contraceptives at the site will be calculated for each bid after allowing for reasonable international and inland transportation time. A delivery "adjustment" will be calculated for and added to each bid by applying a percentage, specified in the BDS, of the EXW/CIF/CIP price for each week of delay beyond the expected time of arrival specified in the Bidding Documents for evaluation purposes. No credit shall be given to early delivery.

or

(ii) The contraceptives covered under these Bidding Documents are required to be delivered (shipped) within an acceptable range of weeks specified in the Schedule of Requirements. No credit will be given to earlier deliveries, and bids offering delivery beyond this range will be treated as nonresponsive. Within this acceptable range, an adjustment per week, as specified in the BDS, will be added for evaluation to the bid price of bids offering deliveries later than the earliest delivery period specified in the Schedule of Requirements.

or

(iii) The contraceptives covered under this invitation are required to be delivered (shipped) in partial shipments, as specified in the Schedule of Requirements. Bids offering deliveries earlier or later than the specified deliveries will be adjusted in the evaluation by adding to the bid price a factor equal to a percentage, specified in the BDS, of EXW/CIF/CIP price per week of variation from the specified delivery schedule.

(b) Deviation in payment schedule.

(i) Bidders shall state their bid price for the payment schedule outlined in the SCC. Bids will be evaluated on the basis of this base price. Bidders are, however, permitted to

state an alternative payment schedule and indicate the reduction in bid price they wish to offer for such alternative payment schedule. The purchaser may consider the alternative payment schedule offered by the selected bidder.

or

(ii) The SCC stipulates the payment schedule offered by the purchaser. If a bid deviates from the schedule and if such deviation is permitted in the BDS, the bid will be evaluated by calculating interest earned for any earlier payments involved in the terms outlined in the bid as compared with those stipulated in this invitation, at the rate per annum specified in the BDS.

(c) Other specific additional criteria to be considered in the evaluation and the evaluation method shall be detailed in the BDS and/or in the Technical Specifications.

31. Domestic Preference

31.1 If indicated in the BDS and for the purpose of bid comparison, the purchaser will grant a margin of preference to contraceptives manufactured in the purchaser's country. This margin of preference will be granted in accordance with the procedures outlined in subsequent paragraphs, provided the bidder shall have established to the satisfaction of the purchaser and of the Bank that its bid complies with the criteria specified in ITB Paragraph 13.2 (a).

31.2 The purchaser will first review the bids to confirm the appropriateness of, and to modify if necessary, the bid group classification to which bidders assigned their bids in preparing their Bid Forms and Price Schedules.

31.3 All evaluated bids in each group will then be compared among themselves to determine the lowest evaluated bid of each group. The lowest evaluated bid of each group will next be compared with the lowest evaluated bids of the other groups. If this comparison results in a bid from Group A or Group B being the lowest, it will be selected for Contract award.

31.4 If, as a result of the preceding comparison, the lowest evaluated bid is from Group C, all Group C bids will then be further compared with the lowest evaluated bid from Group A, after adding to the evaluated bid price of the imported contraceptives offered in each Group C bid, for the purpose of this further comparison only, a flat rate of fifteen (15) percent of the CIF (or CIP border point or CIP named place of destination, as the case may be) bid price of such contraceptives.

Domestic preference will be applied only to those items indicated in the Schedule of Requirements that meet the criteria under Paragraph 15.2 (a).

If the Group A bid in the further comparison is the lowest, it will be selected for award. If not, the lowest evaluated bid from Group C, as determined from the comparison under ITB sub-clause 31.3 above, will be selected for award.

F. Award of Contract

32. Post-qualification

32.1 In the absence of pre-qualification, the purchaser will determine to its satisfaction whether the bidder that is selected as having submitted the lowest evaluated responsive bid is qualified to perform the Contract satisfactorily, in accordance with the criteria listed in ITB sub-clause 5.1 and any additional post-qualification criteria stated in the BDS. If a pre-qualification process

was undertaken for the Contract(s) for which these Bidding Documents were issued, the purchaser will determine in the manner described above that no material changes have occurred after the pre-qualification that negatively affect the ability of the bidder that has submitted the lowest evaluated bid to perform the Contract.

32.2 The determination will evaluate the bidder's financial, technical and production capabilities. It will be based on an examination of the documentary evidence of the bidder's qualifications submitted by the bidder, pursuant to ITB sub-clause 5.1, as well as other information the purchaser deems necessary and appropriate.

32.3 An affirmative post-qualification determination will be a pre-requisite for award of the contract to the lowest evaluated bidder. A negative determination will result in rejection of the bidder's bid, in which event the purchaser will proceed to the next-lowest evaluated bidder to make a similar determination of that bidder's capabilities to perform satisfactorily.

33. Award Criteria

33.1 Pursuant to ITB clauses 30, 31 and 36, the purchaser will award the Contract to the bidder whose bid has been determined to be substantially responsive and has been determined to be the lowest evaluated bid, provided further that the bidder is determined to be qualified to perform the Contract satisfactorily, pursuant to ITB clause 32.

34. Purchaser's Right to Accept Any Bid and to Reject Any or All Bids

34.1 The purchaser reserves the right to accept or reject any bid, or to annul the bidding process and reject all bids at any time prior to contract award, without thereby incurring any liability to the affected bidder or bidders.

35. Purchaser's Right to Vary Quantities at Time of Award

35.1 The purchaser reserves the right at the time of Contract award to increase or decrease, by the percentage indicated in the BDS, the quantity of contraceptives beyond that originally specified in the Schedule of Requirements without any change in unit price or other terms and conditions.

36. Notification of Award

36.1 Prior to the expiration of the period of bid validity, the purchaser will notify the successful bidder in writing by registered letter or by cable, to be subsequently confirmed in writing by registered letter, that its bid has been accepted.

36.2 The notification of award will constitute the formation of the Contract.

36.3 Upon the successful bidder's furnishing of the signed Contract Form and performance security pursuant to ITB clause 38, the purchaser will promptly notify each unsuccessful bidder and will discharge its bid security, pursuant to ITB clause 17.

36.4 If, after notification of award, a bidder wishes to ascertain the grounds on which its bid was not selected, it should address its request to the purchaser. The purchaser will promptly respond in writing to the unsuccessful bidder.

36.5 The purchaser shall publish in the *United Nations Development Business* online and in the international advertisement websites the results identifying the bid and lot numbers and the following information: (i) name of each bidder who submitted a Bid; (ii) bid prices as read out at bid opening; (iii) name and evaluated prices of each Bid that was evaluated; (iv) name of bidders

whose bids were rejected and the reasons for their rejection; and (v) name of the winning bidder, and the price it offered, as well as the duration and summary scope of the contract awarded. After publication of the award, unsuccessful bidders may request in writing to the purchaser for a debriefing seeking explanations on the grounds on which their bids were not selected. The purchaser shall promptly respond in writing to any unsuccessful bidder who, after Publication of contract award, requests a debriefing.

37. Signing of Contract

37.1 Promptly after the purchaser notifies the successful bidder that its bid has been accepted, the purchaser will send the bidder the Contract Form provided in the Bidding Documents, incorporating all agreements between the parties.

37.2 Within twenty eight (28) days of receipt of the Contract Form, the successful bidder shall sign and date the Contract Form and return it to the purchaser.

38. Performance Security

38.1 Within twenty eight (28) days of the receipt of notification of award from the purchaser, the successful bidder shall furnish the performance security in accordance with the Conditions of Contract, using the Performance Security Form provided in the Bidding Documents, or in another form acceptable to the purchaser.

38.2 Failure of the successful bidder to comply with the requirement of ITB clause 37 or ITB sub-clause 38.1 shall constitute sufficient grounds for the annulment of the award and forfeiture of the bid security, in which event the purchaser may make the award to the next-lowest evaluated bid submitted by a qualified bidder or call for new bids.

Notes on the Bid Data Sheet Form

The BDS 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 BDS 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 BDS must be used as a base, dependent upon the type of contraceptives being procured. For example, if changes or additions are made to the BDS 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.

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 BDS shall prevail over those in the ITB.

A. General

ITB 1.1

Name of purchaser: *(insert: name of purchaser).*

Name of authorized Purchasing Agent: *(if appropriate, insert: name of the Purchasing Agent, otherwise state: "none").*

Type of contraceptives: *(insert pharmaceuticals (including nutritional supplements and oral or injectable hormonal contraceptive), vaccines or condoms).*

Name and identification number of the Contract: *(insert: name and identification number of the Contract).*

ITB 4.1 (c)

Documentation requirements for eligibility of contraceptives. In addition to the documents stated in clause 6.2 and 6.3 (a) and (b), the following documents should be included with the Bid: *(Insert: any other eligibility documentation required)*

ITB 4.2

The purchaser's country *(Insert: does or does not)* require registration of contraceptives.

(Note: If the purchaser's country does not require registration of the contraceptives, delete

4.2 (b) and 4.2.1 below and insert the following language:

ITB sub-clause 4.2 is inapplicable. The Applicable Law does not require registration of the contraceptives to be supplied under the Contract.)

ITB 4.2 (b)

By the time of Contract signing, the successful bidder shall have complied with the following documentary requirements in order to register the contraceptives to be supplied under the Contract: *(insert: specific documentary requirements or any other country specific requirement).*

Note: Because of the potential for delay when various government agencies must intervene in the registration process, bidders are alerted to inquire about registration requirements and procedures as early as possible.

ITB 4.2.1

For the purpose of obtaining additional information about the requirements for registration, bidders may contact *(insert: name of agency, contact person, phone/fax/email address).*

ITB 5.1 (a)

Qualification requirements for bidders are:

insert, as appropriate: quantifiable qualification criteria for experience and / or financial viability).

The following documents must be included with the bid:

Documentary evidence of the bidder's qualifications to perform the Contract if its bid is accepted:

(i) that, in the case of a bidder offering to supply contraceptives under the Contract that the bidder manufactures or otherwise produces (using ingredients supplied by primary manufacturers), evidence that the bidder:

(a) is incorporated in the country of manufacture of the contraceptives;
(b) has been licensed by the regulatory authority in the country of manufacture to supply the contraceptives;
(c) has manufactured and marketed the specific contraceptives covered by this Bidding Document for at least two (2) years and for similar contraceptives for at least five (5) years;
(d) has received a satisfactory GMP inspection certificate in line with the WHO certification scheme on pharmaceuticals moving in International Commerce from the regulatory authority (RA) in the country of manufacture of the contraceptives or has been certified by the competent authority of a member country of the Pharmaceuticals Inspection Convention (PIC), and has demonstrated compliance with the quality standards during the past two years prior to bid submission;

(ii) that, in the case of a bidder offering to supply contraceptives under the Contract, the bidder does not manufacture or otherwise produce:

(a) that the bidder has been duly authorized by a manufacturer of the contraceptives that meets the criteria under (i) above to supply the contraceptives in the purchaser's country; and

The bidder shall also submit the following additional information:

(a) (a) a statement of installed manufacturing capacity;
(b) (b) copies of its audited financial statements for the past three fiscal years;
(c) (c) details of on-site QC laboratory facilities and services and range of tests conducted;
(d) (d) list of major supply contracts conducted within the last five years.

B. The Bidding Documents

ITB 9.1

Purchaser's / duly authorized Purchasing Agent's address: (insert: purchaser's address, telephone, telex, and facsimile numbers; also specify a responsible contact person or officer to whom bidder communications should be addressed).

C. Preparation of Bids

ITB 11.1

The language of the bid is: (Insert "*English*" or" *Spanish*" or "*French*").

(In countries that the Bank has agreed with the Borrower that in addition to one internationally used language, bids may be also issued in the language of the Borrower's country (or the language used nationwide in the Borrower's country for commercial transactions), the following text shall be added:

"In addition to the above indicated language, these Bidding Documents have been issued in (insert the language of the Borrower's country or the language used nation-wide in the Borrower's Country for commercial transactions).

Bidders are permitted, at their choice, to submit their bids in one of the two languages above indicated. Bidders shall not submit bids in more than one language. The Contract to be signed with the winning bidder shall be written in the language in which the Bid was submitted, which will be the language that shall govern the contractual relations between the purchaser and the winning bidder. A bidder shall not sign a translated version of its Contract").

ITB 12.1 (i) In addition to the documents stated in Paragraphs 12.1 (a) through (h), the following documents must be included with the Bid *(insert: list of documents*):

(*Sample clause*)

Bidders who are not primary manufacturers should provide evidence that their product conforms to the quality standards of the primary manufacturer and they have the capacity to supply the specified quantities. A "primary manufacturer" is defined as a company that performs all the manufacturing and formulating operations needed to produce pharmaceuticals or nutritional supplements in their appropriate dosage forms, including processing, blending, formulating, filling, packing, labeling and quality testing. The bidder shall furnish a certificate from the competent Regulatory Authority (RA) that the manufacturer is licensed to manufacture the contraceptives offered.

ITB 14.2 (b) (i) and (c) (iii)

Place of Destination: (*insert name of destination as per Inco term used*)

ITB 14.2 (a) (iii) ;(b) (ii) and (c) (v)

"Final destination/site": (*insert name of location where the contraceptives are to be actually used*)

ITB 14.2 (b) (iii)

In addition to the CIP price specified in ITB 14.2 (b)(i), the price of the contraceptives manufactured outside the purchaser's Country shall be quoted: (*insert appropriate Incoterm, other than CIP*)

ITB 14.5

Prices quoted by the bidder shall be (state: "fixed"; or, if a price adjustment mechanism is required, then specify the exact formula that will apply, including the nature of the indices that will be used).

ITB 14.6

Bids are being invited for (indicate "one or more items," or "individual contracts (lots)")

ITB 15.1 (b)

The currency to be used for quoting prices of the contraceptives and Services components of the contraceptives offered from within the purchaser's country, as well as local currency expenditures for local technical support, training, maintenance, transportation, insurance, and other local costs incidental to delivery, is: *(select: currency of purchaser's country / other currency, as specified by the purchaser*).

Note: Bid prices are usually lower if bidders are allowed to quote and be paid in either the currency of expenditure or another internationally traded currency of their choice.

Normally the currency of bid and payment for locally supplied contraceptives is the currency of the purchaser's country. However, Borrowers may allow domestic bidders to bid in a stable foreign currency for their local costs. Alternatively, they may allow those prices to be adjusted. If payments must be made in the local currency to conform to local law or regulation, any such payments due to a

domestic Supplier are converted from the currency of bid to local currency at the exchange rate prevailing at the time of payment.

The presence of such restriction on the currency of payment for locally supplied contraceptives, as well as the precise method of selecting the exchange rate to use in such a case (i.e., the date/time and source of the exchange rate), must be specified in the SCC regarding payment, along with the presence of such restrictions on the currency of payment for locally supplied contraceptives.

ITB 16.1

The bid validity period shall be (insert: number (X) days after the deadline for bid submission, as specified below in reference to ITB clause 21. Accordingly, each bid shall be valid *through (insert: the actual date of the expiration of the bid validity period (i.e., X days after the date of bid opening).*

Note: The bid validity period should be sufficient to permit completion of the evaluation, review of the recommended award by the management of the implementing agency and the Bank, the receipt of all necessary approvals, including the Bank's no objection and issuance of the notification of award. In most cases, ninety (90) days should be adequate, but whatever period is selected, it should be realistic so that requests for extensions are kept to the minimum.

Bid security must be valid twenty-eight (28) days after the end of the bid validity period. Accordingly, a bid with a bid security that expires before (insert: the actual ***d***ate of the expiration of the bid security, i.e., twenty-eight (28) days after the end of the bid validity period) shall be rejected as nonresponsive.

Note: Bank experience also shows that many bids are rejected on the basis of simple errors in calculating the bid security validity period. Accordingly, the purchaser should explicitly state above the date through which bid security must be valid.

ITB 17.1

(Insert one of the following options:

No Bid Security is required; or

Bid shall include a Bid Security (issued by bank or surety) included in Section VIII Sample Forms; or

(c) Bid shall include "Bid Securing Declaration" using the form included in Section VIII Sample Forms.)

The amount of bid security required is: (*insert: fixed amount and currency*).

Note: The amount may be expressed as either a fixed amount or an amount "not less than" a specified percentage of the bidder's bid price. To avoid premature disclosure of bid prices by commercial bank personnel or others, a fixed amount of not less than 2 percent to no more than 3 percent of the budget estimate for the contract (estimated) bid amount is strongly recommended. (Requiring higher bid security risks driving away potentially qualified bidders.) Asking for smaller, or even no bid security at all, however, is acceptable for simple contracts where the market is relatively stable and mature.

Also, in the case of Bidding Documents covering multiple lots, a bid security should be specified as representing not less than "x" percent of the total Bid Price for all lots covered by the bid.

ITB 17.8

If the bidder incurs any of the actions prescribed in subparagraphs (a) or (b) of this provision, the Borrower will declare the bidder ineligible to be awarded contracts by the Employer for a period of _____ years.

ITB 18.1

Alternative bids (*indicate: will or will not*) be accepted.

Note: When bidders are permitted to submit alternative bids, only the alternative submitted by the bidder whose basic bid is the lowest evaluated bid will be considered. Such alternatives will be evaluated in accordance with the evaluation criteria and methods specified in this BDS. An alternative bid can be selected for award only if it was submitted by the bidder whose basic bid is the lowest evaluated bid. The alternative bid must be fully responsive to the requirements specified in the BDS, the SCC and the Specifications of the Bidding Documents and the lowest evaluated bid when compared with the basic bid submitted by the bidder.

The evaluation criteria are (*insert: criteria*).

Requirements for responsive bids are (insert: requirements).

ITB 19.1

Required number of copies of the bid: (*insert: number (X) of copies*).

D. Submission of Bids

ITB 20.1

Bidders (*insert "shall" or "shall not"*) have the option of submitting their bids electronically.

If bidders shall have the option of submitting their bids electronically, the electronic bidding submission procedures shall be: (*insert a description of the electronic bidding submission procedures*)

ITB 20.2 (b)

The address for bid submission is: (*insert: address adequate for mail, courier, or physical delivery, including responsible officer or person).*

Note: Do not use a postal box or similar address.

ITB 20.2 (c) & (d)

See the data above for ITB 1.1 for the name of the Contract.

The IFB title and number are: (*if applicable, insert: Invitation for Bids Title and Invitation for Bids Number (if any); otherwise, state "none"*).

See the data below for ITB 21.1 for the deadline for bid submission.

Note: The purchaser should establish a clear and recognizable numbering system for its Contracts. Failure to do so typically results in misunderstandings in routine communications, review delays and inadequate monitoring of overall project progress.

ITB 21.1

See the data above for ITB sub-clause 20.2 (b) for the address and deadline for bid submission.

Deadline for bid submission is: (*insert: date and time*).

Note: The bid submission date is generally six to twelve weeks from the date of issuance of the Bidding Documents, depending on the value, scope and/or complexity of the contraceptives being purchased.

ITB 22.1

See the data above for ITB sub-clause 21.1 for the deadline for bid submission.

ITB 25.2 (a)

The required number of copies of bid modifications is the same as the number of copies of the original bid specified above in the data for ITB sub-clause 19.1.

ITB 23.3 (a)

See the data above for ITB Paragraph 20.2 (b) for the address to use for submission of a bid withdrawal notice.

E. Bid Opening and Evaluation

ITB 24.1

Time, date and place for bid opening are: (*insert: time, date, and place*).

If electronic bid submission is permitted, in accordance with ITB sub-clause 20.1, the specific bid opening procedures shall be: (*insert description of the procedures*)

Note: 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.

ITB 29.3

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*).

ITB 30.4 (d)

The evaluation will take into account *(insert: factors and other specific criteria*).

ITB 30.5

The factors retained pursuant to ITB sub-clause 30.4 and the quantification methods are: (*insert: factors*).

ITB 30.5 (b) (i) (ii) & (iii)

Delivery schedule (specify: relevant parameters in accordance with option selected).

The adjustment per week for delivery delays beyond the time specified in the Schedule of Requirements is (*specify: adjustment in percentage*).

Or

The adjustment per week for delivery delays beyond the range of weeks specified in the Schedule of Requirements is (*specify: adjustment in percentage*).

Or

The adjustment for partial shipments is (specify: adjustments for early and late deliveries). Note: For evaluation purposes, a rate of one-half (0.5) percent per week is a reasonable figure.

ITB 30.5 (c) (ii)

The purchaser *(select: will / will not*) accept deviations in the payment schedule in the SCC.

Note: If deviations are accepted, add the following text.

The percentage adjustment for payment schedule deviations is: (*insert: percentage*) % per week.

Note: If inflation expectations widely diverge between local and foreign currencies, and bidders are expected to quote significant amounts in local currencies, different adjustment rates for local and foreign currency prices should be provided.

ITB 30.5 (d) (*insert: other factors to be used in the evaluation and their evaluation method or reference to the Technical Specifications*)

Evaluation criteria for items/lots

(Select one of the two sample clauses below)

If bids have been invited for items only, the BDS should state the following:

Bidders may bid for any one or more items. Bids will be evaluated for each item and the Contract will comprise the item(s) awarded to the successful bidder.

If lots will be accepted, the BDS should state the following:

Bidders can bid for one or more lots. Bids will be evaluated lot by lot. Bidders must quote for the entire quantity of each item and at least eighty percent (80%) of the number of items in the lot to be treated as substantially responsive.

Bid evaluation of such bids will be carried out as per the following procedures. The average price of an item quoted by substantially responsive bidders will be added to the bid price of those who did not quote for that item and the equivalent total cost of the bid so determined will be used for bid comparison, evaluation, and award.

ITB 31.1

A margin of domestic preference (*specify: will or will not*) apply.

F. Post-qualification and Award of Contract

ITB 32.1

Post-qualification

(*Insert: Any specific post-qualification requirements, such as the required number of years of manufacturing experience.*)

ITB 35.1 Percentage for increase or decrease of quantity of contraceptives originally specified: *(insert: percentage not more than 20%*).

Bid Data Sheet

Pharmaceuticals

(Additional clauses)

(Note: The below data should be included in the BDS used in Bidding Documents for the procurement of pharmaceuticals.)

ITB 4.3 (c)

(*Sample clauses*)

The contraceptives offered should meet the specified pharmacopoeia 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 5.1 (a) & (d)

Documentary evidence of the bidder's qualifications to perform the Contract if its bid is accepted:

(ii)

(d) has a Good Distribution Practice (GDP) Certificate where appropriate.

The bidder will submit the following additional information:

(e) list of pharmaceuticals being manufactured by the bidder with product registration/license number and date.

(f) a Certificate of Pharmaceutical Product as recommended by the WHO for each item offered.

Notes on the General Conditions of Contract

The 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.

General Conditions of Contract

1. Definitions

1.1 In this Contract, the following terms shall be interpreted as indicated:

(a) "The Contract" means the agreement entered into between the purchaser and the Supplier, as recorded in the Contract Form signed by the parties, including all attachments and appendices thereto and all documents incorporated by reference therein.

(b) "The Contract Price" means the price payable to the Supplier under the Contract for the full and proper performance of its contractual obligations.

(c) "Day" means calendar day.

(d) "Effective Date" means the date on which this Contract becomes effective pursuant to GCC clause 6.2.

(e) "End User" means the organization(s) where the contraceptives will be used, as named in the SCC.

(f) "GCC" means the General Conditions of Contract contained in this section.

(g) "The contraceptives" means all oral and injectable forms of contraception as well as intrauterine device (IUDs) and condoms that the Supplier is required to supply to the purchaser under the Contract.

(h) "The purchaser" means the organization purchasing the contraceptives, as named in the SCC.

(i) "The purchaser's country" is the country named in the SCC.

(j) "Registration Certificate" means the certificate of registration or other documents in lieu thereof establishing that the contraceptives supplied under the Contract are registered for use in the purchaser's country in accordance with the Applicable Law.

(k) "SCC" means the Special Conditions of Contract.

(l) "The Services" means those services ancillary to the supply of the contraceptives, such as transportation and insurance, and any other incidental services, such as provision of technical assistance, training and other such obligations of the Supplier covered under the Contract.

(m) "The Site," where applicable, means the place or places named in the SCC.

(n) "The Supplier" means the individual or firm supplying the contraceptives under this Contract, as named in the SCC.

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. Standards

3.1 The contraceptives supplied under this Contract shall conform to the standards mentioned in the Technical Specifications and, when no applicable standard is mentioned, to the authoritative standards appropriate to the contraceptives' country of origin. Such standards shall be the latest

issued by the concerned institution.

4. Use of Contract Documents and Information; Inspection and Audit by the purchaser

4.1 The Supplier shall not, without the purchaser's prior written consent, disclose the Contract, or any provision thereof, or any specification, plan, drawing, pattern, sample or information furnished by or on behalf of the purchaser in connection therewith, to any person other than a person employed by the Supplier in the performance of the Contract. Disclosure to any such employed person shall be made in confidence and shall extend only as far as may be necessary for purposes of such performance.

4.2 The Supplier shall not, without the purchaser's prior written consent, make use of any document or information enumerated in GCC sub-clause 4.1 except for purposes of performing the Contract.

4.3 Any document, other than the Contract itself, enumerated in GCC sub-clause 4.1 shall remain the property of the purchaser and shall be returned (all copies) to the purchaser on completion of the Supplier's performance under the Contract if so required by the purchaser.

4.4 The Supplier shall permit the purchaser and/or persons appointed by the purchaser to inspect the Supplier's offices and/or the accounts and records of the Supplier and its sub-contractors relating to the performance of the Contract. The Supplier's attention is drawn to clause 22 which provides, inter alia, that acts intended to materially impede the exercise of the purchaser's inspection and audit rights provided for under this sub-clause constitute a prohibited practice subject to contract termination.

5. Certification of contraceptives in Accordance with Laws of the purchaser's Country

5.1 If required under the Applicable Law, contraceptives supplied under the Contract shall be registered for use in the purchaser's country. The purchaser undertakes to cooperate with the Supplier to facilitate registration of the contraceptives for use in the purchaser's country.

5.2 Unless otherwise specified in the SCC, the Contract shall become effective on the date ("the Effective Date") that the Supplier receives written notification from the relevant authority in the purchaser's country that the contraceptives have been registered for use in the purchaser's country.

5.3 If thirty (30) days, or such longer period specified in the SCC, elapse from the date of Contract signing and the Contract has not become effective pursuant to sub-clause 5.2 above, then either party may, by not less than seven (7) days' written notice to the other party, declare this Contract null and void. In such event, the Supplier's performance security shall be promptly returned.

6. Patent Rights

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

7. Performance Security

7.1 Within twenty eight (28) days of receipt of the notification of Contract award, the successful bidder shall furnish to the purchaser the performance security in the amount specified in the SCC.

7.2 The proceeds of the performance security shall be payable to the purchaser as

compensation for any loss resulting from the Supplier's failure to complete its obligations under the Contract.

7.3 The performance security shall be denominated in the currency of the Contract, or in a freely convertible currency acceptable to the purchaser, and shall be in one of the following forms:

(a) a bank guarantee or an irrevocable L/C issued by a reputable bank located in the purchaser's country or abroad, acceptable to the purchaser, in the format provided in the Bidding Documents or another format acceptable to the purchaser; or

(b) a cashier's or certified check.

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

8. Inspections and Tests

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

(a) Said inspection and testing is for the purchaser's account. In the event that inspection and testing is required prior to dispatch, the contraceptives shall not be shipped unless a satisfactory inspection and QC report has been issued in respect of those contraceptives.

(b) The Supplier may have an independent quality test conducted on a batch ready for shipment. The cost of such tests will be borne by the Supplier.

(c) Upon receipt of the contraceptives at place of final destination, the purchaser's representative shall inspect the contraceptives or part of the contraceptives to ensure that they conform to the condition of the Contract and advise the purchaser that the contraceptives were received in apparent good order. The purchaser will issue an Acceptance Certificate to the Supplier in respect of such contraceptives (or part of contraceptives). The Acceptance Certificate shall be issued within ten (10) days of receipt of the contraceptives or part of contraceptives at place of final destination.

8.2 Where the Supplier contests the validity of the rejection by the purchaser or his representative, of any inspection as required by 8.1 above conducted before shipment or at ultimate destination, whether based on product or packing grounds, a sample, drawn jointly by the Supplier and purchaser or his or her representative and authenticated by both, will be forwarded for umpire analysis within four weeks of the time the Supplier contests to an independent agency mutually agreed by the purchaser and Supplier. The umpire's finding, which will be promptly obtained, will be final and binding on both parties. The cost of umpire analysis will be borne by the losing party.

9 Packing

9.1 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.

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

10. Delivery and Documents

10.1 Delivery of the contraceptives shall be made by the Supplier in accordance with the terms specified in the Schedule of Requirements. The details of shipping and/ or other documents to be furnished by the Supplier are specified in the SCC.

10.2 For purposes of the Contract, EXW, FOB, FCA, CIF, CIP, and other trade terms used to describe the obligations of the parties shall have the meanings assigned to them by the current edition of Incoterms published by the ICC, Paris.

10.3 Documents to be submitted by the supplier are specified in the SCC. Incoterms provides a set of international rules for the interpretation of the more commonly used trade terms.

11. Insurance

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

11.2 Where delivery of the contraceptives is required by the purchaser on a CIF or CIP basis, the Supplier shall arrange and pay for cargo insurance, naming the purchaser as beneficiary. Where delivery is on an FOB or FCA basis, insurance shall be the responsibility of the purchaser.

12. Transportation

12.1 Where the Supplier is required under Contract to deliver the contraceptives FOB, transport of the contraceptives, up to and including the point of putting the contraceptives on board the vessel at the specified port of loading, shall be arranged and paid for by the Supplier, and the cost thereof shall be included in the Contract Price. Where the Supplier is required under the Contract to deliver the contraceptives FCA, transport of the contraceptives and delivery into the custody of the carrier at the place named by the purchaser or other agreed point shall be arranged and paid for by the Supplier, and the cost thereof shall be included in the Contract Price.

12.2 Where the Supplier is required under Contract to deliver the contraceptives CIF or CIP, transport of the contraceptives to the port of destination or such other named place of destination in the purchaser's country, as shall be specified in the Contract, shall be arranged and paid for by the Supplier, and the cost thereof shall be included in the Contract Price.

12.3 Where the Supplier is required under the Contact to transport the contraceptives to a specified place of destination within the purchaser's country, defined as the Site, transport to such place of destination in the purchaser's country, including insurance and storage, as shall be specified in the Contract, shall be arranged by the Supplier, and related costs shall be included in the

Contract Price.

12.4 Where the Supplier is required under Contract to deliver the contraceptives CIF or CIP, no restriction shall be placed on the choice of carrier. Where the Supplier is required under Contract

(a) to deliver the contraceptives FOB or FCA, and

(b) to arrange on behalf and at the expense of the purchaser for international transportation on specified carriers or on national flag carriers of the purchaser's country, the Supplier may arrange for such transportation on alternative carriers if the specified or national flag carriers are not available to transport the contraceptives within the period(s) specified in the Contract.

13. Incidental Services

13.1 The Supplier shall provide such incidental services, if any, as are specified in the SCC.

13.2 Prices charged by the Supplier for incidental services, if not included in the Contract Price for the contraceptives, shall be agreed upon in advance by the parties and shall not exceed the prevailing rates charged to other parties by the Supplier for similar services.

14. Warranty

14.1All contraceptives must be of fresh manufacture and must bear the dates of manufacture and expiry.

The Supplier further warrants that all contraceptives supplied under the Contract will have remaining a minimum of five-sixths (5/6) of the specified shelf life upon delivery at port/airport of entry for contraceptives with a shelf life of more than two years and three-fourths (3/4) for contraceptives with a shelf life of two years or less, unless otherwise specified in the SCC; 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.

14.2 The purchaser shall have the right to make claims under the above warranty for three months after the contraceptives have been delivered to the final destination indicated in the Contract. Upon receipt of a written notice from the purchaser, the Supplier shall, with all reasonable speed, replace the defective contraceptives without cost to the purchaser. The Supplier will be entitled to remove, at his own risk and cost, the defective contraceptives once the replacement contraceptives have been delivered.

14.3 In the event of a dispute by the Supplier, a counter analysis will be carried out on the manufacturer's retained samples by an independent neutral laboratory agreed by both the purchaser and the Supplier. If the counter analysis confirms the defect, the cost of such analysis will be borne by the Supplier as well as the replacement and disposal of the defective contraceptives. In the event of the independent analysis confirming the quality of the product, the purchaser will meet all costs for such analysis.

14.4 If, after being notified that the defect has been confirmed pursuant to GCC sub-clause 14.2 above, the Supplier fails to replace the defective contraceptives within the period specified in the SCC, the purchaser may proceed to take such remedial action as may be necessary, including removal and disposal, at the Supplier's risk and expense and without prejudice to any

other rights that the purchaser may have against the Supplier under the Contract. The purchaser will also be entitled to claim for storage in respect of the defective contraceptives for the period following notification and deduct the sum from payments due to the Supplier under this Contract.

14.5 Recalls. In the event any of the contraceptives are recalled, the Supplier shall notify the purchaser within fourteen (14) days, providing full details of the reason for the recall and promptly replace, at its own cost, the items covered by the recall with contraceptives that fully meet the requirements of the Technical Specification and arrange for collection or destruction of any defective contraceptives. If the Supplier fails to fulfill its recall obligation promptly, the purchaser will, at the Supplier's expense, carry out the recall.

15. Payment

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

15.2 The Supplier's request(s) for payment shall be made to the purchaser in writing, accompanied by an invoice describing, as appropriate, the contraceptives delivered and Services performed, and by documents submitted pursuant to GCC clause 10, and upon fulfillment of other obligations stipulated in the Contract.

15.3 Payments shall be made promptly by the purchaser, but in no case later than sixty (60) days after submission of an invoice or claim by the Supplier.

15.4 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.

15.5 All payments shall be made in the currency or currencies specified in the SCC pursuant to GCC 15.4.

16. Prices

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

17. Change Orders

17.1 The purchaser may at any time, by a written order given to the Supplier pursuant to GCC clause 30, make changes within the general scope of the Contract in any one or more of the following:

(a) specifications, where contraceptives to be furnished under the Contract are to be specifically manufactured for the purchaser;

(b) the method of shipment or packing;

(c) the place of delivery; and/or

(d) the Services to be provided by the Supplier.

17.2 If any such change causes an increase or decrease in the cost of, or the time required for, the Supplier's performance of any provisions under the Contract, an equitable adjustment shall be made in the Contract Price or delivery schedule, or both, and the Contract shall accordingly

be amended. Any claims by the Supplier for adjustment under this clause must be asserted within thirty (30) days from the date of the Supplier's receipt of the purchaser's change order.

18. Contract Amendments

18.1 Subject to GCC clause 17, no variation in or modification of the terms of the Contract shall be made except by written amendment signed by the parties.

19. Assignment

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

20. Delays in the Supplier's Performance

20.1 Delivery of the contraceptives and performance of Services shall be made by the Supplier in accordance with the time schedule prescribed by the purchaser in the Schedule of Requirements.

20.2 IfatanytimeduringperformanceoftheContract,theSupplieroritssubcontractor(s) should encounter conditions impeding timely delivery of the contraceptives and performance of Services, the Supplier shall promptly notify the purchaser 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 purchaser shall evaluate the situation and may at its discretion extend the Supplier's time for performance, with or without liquidated damages (L/D), in which case the extension shall be ratified by the parties by amendment of Contract.

20.3 Except as provided under GCC clause 23, a delay by the Supplier in the performance of its delivery obligations shall render the Supplier liable to the imposition of L/D pursuant to GCC clause 21, unless an extension of time is agreed upon pursuant to GCC clause 20.2 without the application of the L/D.

21. Liquidated Damages

21.1 Subject to GCC clause 23, if the Supplier fails to deliver any or all of the contraceptives or to perform the Services within the period(s) specified in the Contract, the purchaser shall, without prejudice to its other remedies under the Contract, deduct from the Contract Price, as L/D, a sum equivalent to the percentage specified in the SCC of the delivered price of the delayed contraceptives or unperformed Services for each week or part thereof of delay until actual delivery or performance, up to a maximum deduction of the percentage specified in the SCC. Once the maximum is reached, the purchaser may consider termination of the Contract pursuant to GCC clause 22.

22. Termination for Default

22.1 The purchaser, without prejudice to any other remedy for breach of Contract, by written notice of default sent to the Supplier, may terminate this Contract in whole or in part:

(a) if the Supplier fails to deliver any or all of the contraceptives within the period(s) specified in the Contract, or within any extension thereof granted by the purchaser pursuant to GCC clause 20; or

(b) if the contraceptives do not meet the Technical Specifications stated in the Contract; or

(c) if the Supplier fails to provide any registration or other certificates in respect of the

contraceptives within the time specified in the Special Conditions.

(d) if the purchaser determines that the Supplier has engaged in corrupt, fraudulent, collusive, coercive or obstructive practices in competing for or in executing the Contract, then the purchaser may, after giving 14 days notice to the Supplier, terminate the Supplier's employment under the Contract and cancel the contract, and the provisions of clause 22 shall apply as if such expulsion had been made under sub-clause 22.1.

For the purposes of this sub-clause:

(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 influencing 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

(aa) 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; or

(bb)acts intended to materially impede the exercise of the Bank's inspection and audit rights provided for under clause 5.

(e) should any employee of the Supplier be determined to have engaged in corrupt, fraudulent, collusive, coercive or obstructive practice during the purchase of the contraceptives, then that employee shall be removed.

(f) if the Supplier fails to perform any other obligation(s) under the Contract.

22.2 In the event the purchaser terminates the Contract in whole or in part, pursuant to GCC clause 22.1, the purchaser may procure, upon such terms and in such manner as it deems appropriate, contraceptives or Services similar to those undelivered, and the Supplier shall be liable to the purchaser for any excess costs for such similar contraceptives or Services. However, the Supplier shall continue performance of the Contract to the extent not terminated.

23. *Force Majeure*

23.1 Notwithstanding the provisions of GCC clauses 20, 21, and 22, the Supplier shall not be liable for forfeiture of its performance security, L/D or termination for default if and to the extent that its delay in performance or other failure to perform its obligations under the Contract is the result of an event of *force majeure*.

23.2 For purposes of this clause, "*force majeure*" means an event beyond the control of the Supplier and not involving the Supplier's fault or negligence and not foreseeable. Such events

may include, but are not restricted to, acts of the purchaser in its sovereign capacity, wars or revolutions, fires, floods, epidemics, quarantine restrictions and freight embargoes.

23.3 If *a force majeure*situation arises, the Supplier shall promptly notify the purchaser in writing of such condition and the cause thereof. Unless otherwise directed by the purchaser in writing, the Supplier shall continue to perform its obligations under the Contract as far as is reasonably practical and shall seek all reasonable alternative means for performance not prevented by the force majeure event.

24. Termination for Insolvency

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

25. Termination for Convenience

25.1 The purchaser, by written notice sent to the Supplier, may terminate the Contract, in whole or in part, at any time for its convenience. The notice of termination shall specify that termination is for the purchaser's convenience, the extent to which performance of the Supplier under the Contract is terminated and the date upon which such termination becomes effective.

25.2 The contraceptives that are complete and ready for shipment within thirty (30) days after the Supplier's receipt of notice of termination shall be accepted by the purchaser at the Contract terms and prices. For the remaining contraceptives, the purchaser 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 contraceptives and Services and for materials and parts previously procured by the Supplier.

26. Settlement of Disputes

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

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

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

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

26.3 Notwithstanding any reference to arbitration herein,

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

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

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 purchaser, whether in contract, tort or otherwise, for any indirect or consequential loss or damage, loss of use, loss of production or loss of profits or interest costs, provided that this exclusion shall not apply to any obligation of the Supplier to pay L/D to the purchaser; and

(b) the aggregate liability of the Supplier to the purchaser, whether under the Contract, in tort or otherwise, shall not exceed the total Contract Price, provided that this limitation shall not apply to the cost of repairing or replacing defective equipment.

28. Governing Language

28.1 The Contract shall be written in the language specified in the SCC. Subject to GCC clause 30, the version of the Contract written in the specified language shall govern its interpretation. All correspondence and other documents pertaining to the Contract that are exchanged by the parties shall be written in the same language.

29. Applicable Law

29.1 The Contract shall be interpreted in accordance with the laws of the purchaser's country, unless otherwise specified in the SCC.

30. Notices

30.1 Any notice given by one party to the other pursuant to this Contract shall be sent to the other party in writing or by cable, telex or facsimile and confirmed in writing to the other party's address specified in the SCC.

30.2 A notice shall be effective when delivered or on the notice's effective date, whichever is later.

31. Taxes and Duties

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

31.2 A Supplier supplying contraceptives offered locally shall be entirely responsible for all taxes, duties, license fees, etc., incurred until delivery of the contracted contraceptives to the purchaser.

Notes on the Special Conditions of Contract

Similar to the BDS, 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 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

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

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

GCC 1.1 (g)

The purchaser is: (insert: name of purchaser).

GCC 1.1 (h)

The purchaser's country is: (insert: name of purchaser's country).

GCC 1.1 (i)

The Supplier is: (insert: name of Supplier).

GCC 1.1 (k)

The Site is/are: (insert, if applicable: identity of Site, street address and city, or insert: "as specified in the Schedule of Requirements").

GCC 1.1 (m)

The end user is: (insert, if applicable: the organization(s) stated in the Schedule of Requirements, where the contraceptives will be used).

GCC 5.1

The registration and other certification necessary to prove registration in purchaser's country is (insert: details of registration and other certification necessary to prove registration in purchaser's country.)

GCC 5.2

The Effective Date of the Contract is (insert: date of Contract signing if EITHER: (i) the contraceptives have already been registered at the time of Contracting signing OR (ii) registration of the contraceptives is not a requirement under the Applicable Law. Otherwise, delete and insert "NOT USED.")

GCC 5.3

The time period shall be (insert: a number greater than 30) days.

(If not used, delete and insert "NOT USED.")

GCC 7.1

Performance security shall be for an amount equal to (insert: number).

Note: Five (5) to ten (10) percent of the Contract Price is a reasonable amount.

GCC 7.4

Any additional requirements related to the discharge of performance security are (insert: any additional requirement related to the discharge of the performance security, or state: "There are no Special Conditions of Contract applicable to GCC sub-clause 7.4").

GCC 8.1

(Insert: any additional requirement related to the inspections and tests, or state: "There are no Special Conditions of Contract applicable to GCC sub-clause 8.")

GCC 9.2

(Insert: Any necessary additional requirements with respect to packing and marking or state that additional requirements are indicated in the Technical Specifications.)

GCC 10.1 & 10.3

Sample provision (CIF/CIP terms)

For contraceptives supplied from abroad:

Upon shipment, the Supplier shall notify the purchaser and the insurance company in writing the full details of the shipment, including Contract number, description of the contraceptives, quantity, date and place of shipment, mode of transportation and estimated date of arrival at place of destination. In the event of contraceptives sent by airfreight, the Supplier shall notify the purchaser a minimum of forty-eight (48) hours ahead of dispatch, the name of the carrier, the flight number, the expected time of arrival and the waybill number. The Supplier shall fax and then send by courier the following documents to the purchaser, with a copy to the insurance company:

(i) three originals and two copies of the Supplier's invoice, showing purchaser as (enter correct description of purchaser for customs purposes); the Contract number, contraceptives description, quantity, unit price and total amount. Invoices must be signed in original, stamped, or sealed with the company stamp/seal;

(ii) one original and two copies of the negotiable, clean, on-board through bill of lading marked "freight prepaid" and showing purchaser as (enter correct name of purchaser for customs

purposes) and Notify Party as stated in the Contract, with delivery through to final destination as per the Schedule of Requirements and two copies of non-negotiable bill of lading, or three copies of railway consignment note, road consignment note, truck or air waybill, or multimodal transport document, marked "freight prepaid" and showing delivery through to final destination as per the Schedule of Requirements;

(iii) four copies of the packing list identifying contents of each package;

(iv) copy of the Insurance Certificate, showing the purchaser as the beneficiary;

(v) one original of the manufacturer's or Supplier's Warranty Certificate covering all items supplied;

(vi) one original of the Supplier's Certificate of Origin covering all items supplied;

(vii) original copy of the Certificate of Inspection furnished to Supplier by the nominated inspection agency and six copies (where inspection is required);

(viii) any other procurement-specific documents required for delivery/payment purposes. For contraceptives from within the purchaser's country:

Upon or before delivery of the contraceptives, the Supplier shall notify the purchaser in writing and deliver the following documents to the purchaser:

(i) two originals and two copies of the Supplier's invoice, showing purchaser, the Contract number, contraceptives' description, quantity, unit price and total amount. Invoices must be signed in original and stamped or sealed with the company stamp/ seal;

(ii) two copies of delivery note, railway consignment note, road consignment note, truck or air waybill, or multimodal transport document showing purchaser as (enter correct name of purchaser for customs purposes) and delivery through to final destination as stated in the Contract;

(iii) copy of the Insurance Certificate, showing the purchaser as the beneficiary; (iv) four copies of the packing list identifying contents of each package;

(v) one original of the manufacturer's or Supplier's Warranty certificate covering all items supplied;

(vi) one original of the Supplier's Certificate of Origin covering all items supplied;

(vii) original copy of the Certificate of Inspection furnished to Supplier by the nominated inspection agency and six copies (where inspection is required);

(viii) other procurement-specific documents required for delivery/payment purposes.

Note: In the event that the documents presented by the Supplier are not in accordance with the Contract, then payment will be made against issue of the Acceptance Certificate, to be issued in accordance with SCC 8 (GCC 8) above.

GCC 11.1

The insurance shall be in an amount equal to 110 percent of the CIF or CIP value of the contraceptives from "warehouse" to "warehouse" on "All Risks" basis, including war risks and strikes (only if contract placed on CIF or CIP basis).

GCC 13.1

Incidental services to be provided are:

(Sample clauses)

(a) The Supplier shall provide all necessary licenses and permissions for use of the contraceptives in the purchaser's country that may be required for the contraceptives. The cost shall be deemed included in the Contract Price.

(b) The Supplier shall provide such other services as are stated in the Technical Specifications. (insert: sections of the Technical Specifications where the services are listed.)

GCC 14.4

The period for the replacement of defective contraceptives is: (insert period for replacement of defective contraceptives).

GCC 15.1 & 15.4

(Sample provision)

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

Payment for contraceptives supplied from abroad:

Payment of foreign currency portion shall be made in (insert: currency of the Contract Price) in the following manner:

(i) Advance Payment: Ten (10) percent of the Contract Price shall be paid within thirty

(30) Days of signature of Contract and receipt of the Performance Guarantee, upon submission of an invoice (showing purchaser's name; the Contract number, loan number; description of payment and total amount, signed in original, stamped or sealed with the company stamp/seal) and a bank guarantee in the form provided in Section VIII, Advance Payment Bank Guarantee.

(ii) On Shipment: Eighty (80) percent of the Contract Price of the contraceptives shipped shall be paid through irrevocable confirmed L/C opened in favor of the Supplier in a bank in its country, upon submission of documents specified in GCC clause 11 or, alternatively, at the Supplier's option, within thirty (30) days of submission of documents specified in GCC clause 11 above by direct bank transfer to the Supplier's nominated bank account. Opening charges and charges for amendment of the L/C at the request of or due to a fault or default of the purchaser are for the account of the purchaser. Confirmation charges and charges for amendment to letters of credit at the request of or due to a fault or default on behalf of the Supplier are for the account of the Supplier.

(iii) On Acceptance: Ten (10) percent of the Contract Price of contraceptives received shall be paid within thirty (30) days of receipt of the contraceptives upon submission of an invoice (showing purchaser's name; the Contract number, loan number; description of payment and total amount, signed in original, stamped or sealed with the company stamp/seal) supported by the Acceptance Certificate issued by the purchaser.

Payment of local currency portion shall be made in (insert: currency) within thirty (30) days of presentation of an invoice (showing purchaser's name; the Contract number, loan number; description of payment and total amount, signed in original, stamped or sealed with the company stamp/seal) supported by the Acceptance Certificate issued by the purchaser.

Payment for contraceptives and Services supplied from within the purchaser's country:

Payment for contraceptives and Services supplied from within the purchaser's country shall be made in (insert: currency), as follows:

(i) Advance Payment: Ten (10) percent of the Contract Price shall be paid within thirty (30) Days of signature of Contract and receipt of the Performance Guarantee, upon submission of an invoice (showing purchaser's name; the Contract number, loan number; description of payment and total amount, signed in original, stamped or sealed with the company stamp/seal) and a bank guarantee in the form provided in Advance Payment Bank Guarantee.

(ii) On Shipment: Eighty (80) percent of the Contract Price of the contraceptives shipped shall be paid within 30 days of submission of documents specified in GCC clause 10 above by direct bank transfer to the Supplier's nominated bank account.

(iii) On Acceptance: Ten (10) percent of the Contract Price of contraceptives received shall be paid within thirty (30) days of receipt of the contraceptives upon submission of an invoice (showing purchaser's name; the Contract number, loan number; description of payment and total amount, signed in original, stamped or sealed with the company stamp/seal) supported by the Acceptance Certificate issued by the purchaser.

(Please note that percentages may be changed to meet procurement specific requirements or trade norms.)

GCC 16.1

(Sample provision)

Prices shall be fixed and firm for the duration of the Contract.

GCC 21.1

(Insert: applicable rate)

(Insert: maximum deduction)

Note: Applicable rate shall not exceed one-half (0.5) percent per week, and the maximum shall not exceed ten (10) percent of the Contract Price.

GCC 26.2.2

The dispute resolution mechanism to be applied pursuant to GCC sub-clause 26.2.2 shall be as follows:

(a) Contracts with foreign Supplier:

(For Contracts entered into with foreign Supplier, international commercial arbitration may have practical advantages over other dispute settlement methods. The World Bank should not be named as arbitrator, nor should it be asked to name an arbitrator. Among the rules to govern the arbitration proceedings, the Employer may wish to consider the United Nations Commission on International Trade Law (UNCITRAL) Arbitration Rules of 1976, the Rules of Conciliation and Arbitration of the ICC, the Rules of the London Court of International Arbitration or the Rules of Arbitration Institute of the Stockholm Chamber of Commerce.)

If the purchaser chooses the UNCITRAL Arbitration Rules, the following sample clause should be inserted:

GCC 26.2.2 (a) any dispute, controversy or claim arising out of or relating to this Contract, or breach, termination or invalidity thereof, shall be settled by arbitration in accordance with the UNCITRAL Arbitration Rules as at present in force.

If the purchaser chooses the Rules of ICC, the following sample clause should be inserted: GCC 26.2.2 (a) all disputes arising in connection with the present Contract shall be finally settled under the Rules of Conciliation and Arbitration of the ICC by one or more arbitrators appointed in accordance with said Rules.

If the purchaser chooses the Rules of Arbitration Institute of Stockholm Chamber of Commerce, the following sample clause should be inserted:

GCC 26.2.2 (a) any dispute, controversy or claim arising out of or in connection with this Contract, or the breach, termination or invalidity thereof, shall be settled by arbitration in accordance with the Rules of the Arbitration Institute of the Stockholm Chamber of Commerce.

If the purchaser chooses the Rules of the London Court of International Arbitration, the following clause should be inserted:

GCC 26.2.2 (a) Any dispute arising out of or in connection with this Contract, including any question regarding its existence, validity or termination shall be referred to and finally resolved by arbitration under the Rules of the London Court of International Arbitration, which rules are deemed to be incorporated by reference to this clause.

(b) Contracts with Supplier national of the purchaser's country:

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

(The bidding documents should contain one clause to be retained in the event of a Contract with a foreign Supplier and one clause to be retained in the event of a Contract with a Supplier who is a national of the purchaser's country. At the time of finalizing the Contract, the respective applicable clause should be retained in the Contract. The following explanatory note should, therefore, be inserted as a header to SCC 26.2.2 in the bidding document.

"clause 26.2.2 (a) shall be retained in the case of a Contract with a foreign Supplier and clause 26.2.2 (b) shall be retained in the case of a Contract with a national of the purchaser's country.")

GCC 28.1(insert: the governing language)

GCC 29.1The Contract shall be interpreted in accordance with the laws of the:

(Insert: name of country).

GCC 30.1 (insert: the purchaser's address for notice purposes) (insert: the Supplier's address for notice purposes)

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.

GCC 10.1 & 10.3

For contraceptives supplied from abroad:

(ix) One original of the Certificate of Pharmaceutical Product as recommended by the WHO

for each of the items supplied.

(x) 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.

(xi) 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 GCC in the procurement of condoms. Whenever there is a conflict, the provisions herein shall prevail over those in the GCC. The corresponding clause number of the GCC is indicated in parentheses.

GCC 8(d)

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 QC 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.

GCC 10.1 & 10.3

For contraceptives supplied from abroad:

(ix) original copy of QC tests for each consignment as stated in SCC 8 above.

(x) 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 nonproprietary 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, and 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 REQUIREMENTS

Product Strength	**A** XX	**B** XX	**C** XX	**D** XX
Quantity in Doses				
Date of Delivery				
No. of Shipments				
Shelf Life*				

*remaining on delivery date

PRICE OFFER

Product	**A**	**B**	**C**	**D**

Please enter prices in US dollars in appropriate boxes

Period of Validity: _____

Signature: _____

Date: _____

For: _____

(Name of company)

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 color 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. 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.

B. Sample Technical Specifications for Contraceptives

This section contains sample technical specifications for contraceptives that can be used by procurement staff when conducting local or international competitive procurement. It is always beneficial to have any technical specification reviewed before release by a technical expert as discussed above.

In the following specifications, examples of actual product specifications are in italics. When preparing procurement specifications, appropriate product specifications should be substituted for the italicized examples. This sample is designed to be used in conjunction with bidding and contract documents.

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:**Preshipment inspection (of physical attributes); Preshipment sampling and testing (for analysis of suspect products)

Technical Specification - Oral Contraceptive

Information for submission of samples

The sample oral contraceptives submitted by the bidder in response to this IFB must be exactly the same[46] 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.[47]

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)

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[46]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.

47 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.

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, 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.[48]

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

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[48]Available at: http://www.who.int/medicines/areas/quality_safety/regulation_legislation/certification/en/index.html.

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
- 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 Color

Background color shall be the natural color 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 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.

1.16 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[49] 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.50

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 (QA) tests on pharmaceutical products according to the Pharmacopoeia specification.

2.4 Sampling Procedures

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[49]Evidence includes quality control and manufacturing records, in-process control records and final product Certificate of Analysis.

[50]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.

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) 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.[51]

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[52]. 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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[51]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.

[52]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[53]:

- 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.[54]

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
- 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*

[53]The smallest type shall be no less than 1 mm high, unless otherwise specified by the commercial laws of the country of importation.

[54]The smallest type shall be no less than 10 mm high, unless otherwise specified by the commercial laws of the country of importation.

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, and 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 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.[55]

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

[55]Immerse package in 0.05 percent methylene blue solution under 15 vacuum gauge for two minutes.Observe for leakage. AQL 2.5%.

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 IFB must be exactly the same as would be supplied if a contract were awarded to the bidder.[56] 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.[57]

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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[56]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.

[57]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 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.[58]

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 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.

[58]Available at: http://www.who.int/medicines/areas/quality_safety/regulation_legislation/certification/en/index.html.

1.11 Workmanship

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 QC authorities the manufacturers' 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[59] 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

[59]Evidence includes quality control and manufacturing records, in-process control records and final product Certificate of Analysis.

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 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.[60]

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*

[60] 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 international pharmacopoeia. Following recognized sampling procedures helps to ensure that the products tested are representative of the whole.

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[61].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[62]:

- 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.[63]

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

[61]The use of additional tape along the joint of the outer lids and around the top and bottom corners willgreatly 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.

[62]The smallest type shall be no less than 1 mm high, unless otherwise specified by the commercial laws of the country of importation.

[63]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, and 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 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 (color, 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

(from WHO document "The Male Latex Condom. Specifications and Guidelines for Condom Procurement :2003")

1. General Requirements

Materials

a) The condoms shall be made of natural rubber latex.
b) 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.
c) Safety assessments shall be conducted in accordance with ISO 10993 or equivalent methods.
d) Manufacturers shall take steps to minimize the level of water-extractable proteins in the condoms.
e) A suitable dusting powder (e.g., cornstarch, magnesium and calcium carbonates) should be used to prevent the condoms from sticking together during manufacture and allow them to unroll easily. Talc or lycopodium spores shall not be used. Manufacturers should not use excess powder (maximum recommended is 50 mg per condom).

Shelf Life

a) Condoms shall comply with the performance requirements of this Technical Specification throughout the stated shelf life of the condom.
b) The manufacturer shall stipulate a shelf life based on the outcome of stability studies and measured from the date of manufacture. This shelf life shall be not less than three years and not more than five years.
c) Shelf life shall be confirmed by real time stability studies conducted at (30-2+5) °C according ISO 4074:2002, Section 7.3. If results from such studies are not available prior to the pre-qualification stage, manufacturers must initiate the studies immediately. Pending the outcome of the real-time studies, manufacturers may rely upon:

   - Accelerated stability studies at elevated temperatures to estimate the shelf life of their products
   - Their own established and validated procedures for establishing shelf life estimates

d) Advice on conducting and analyzing stability studies is in ISO 4074:2002, Section 7.4, Annex K. Data from such studies should be reviewed as part of the pre-qualification procedure. If at any time during the real-time studies the manufacturer becomes aware that the shelf life estimates made using the accelerated studies are incorrect, the purchasers must be notified immediately.

Minimum Stability Requirements

Condoms shall comply with the minimum stability requirements defined in ISO 4074:2002, Section 7.2.

Sampling: Three LOTS sampled in accordance with ISO 2859-1, Inspection Level G-I but at least Code Letter M.

Conditioning: Incubate samples in their individual, sealed containers according to Annex H of ISO 4074:2002; one set for 168 ± 2 hours at 70 ± 2 °C and the other set for 90 ± 1 days at 50 ± 2 °C. At the end of the incubation periods, withdraw the condoms and test for airburst properties.

Testing: In accordance with test method in ISO 4074:2002, Annex G.

Requirement: Minimum bursting requirements:

- AQL 1.5
- Volume
  - 16.0 dm3 for condoms with widths less than 50.0 mm
  - 18.0 dm3 for condoms with widths 50.0 mm up to 56.0 mm
  - 22.0 dm3 for condoms with widths greater than 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 Annex E of ISO 4074: 2002 at a point (75 ± 5) mm from the closed end.

2. Performance Requirements

The performance requirements specified here are based on the requirements of ISO 4074:2002. These requirements cannot be altered. Verification of compliance with these requirements is to be done as part of pre-qualification and the LOT-by-LOT compliance testing of the product.

Bursting Volume and Pressure

Sampling: In accordance with ISO 2859-1, Inspection Level G-I.

Testing: In accordance with test method in ISO 4074:2002, Annex G, clauses 6.1 (before oven conditioning) and 6.2 (after oven conditioning) for (168 ± 2) hours at (70 ± 2) °C.

Requirement: Minimum bursting requirements:

- AQL 1.5
- Volume
  - 16.0 dm3 for condoms with widths less than 50.0 mm
  - 18.0 dm3 for condoms with widths 50.0 mm up to 56.0 mm
  - 22.0 dm3 for condoms with widths greater than 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 ISO 4074:2002, Annex E at a point (75 ± 5) mm from the closed end.

Freedom from Holes and Visible Defects

Sampling: In accordance with ISO 2859-1, Inspection Level G-I but at least Code Letter M.

Testing: In accordance with test method in ISO 4074:2002, Annex L.

- Freedom from holes: AQL 0.25
- Visible defects: AQL 0.4

There is a more detailed discussion on critical and non-critical visible defects in Section 1.

Package Integrity (seal integrity)

Sampling: In accordance with ISO 2859-1, Inspection Level S-3.

Testing: In accordance with test method in ISO 4074:2002, Annex M. Requirement: AQL 2.5

3. Design Requirements

Shape and Texture

a) The surface of the condoms shall be non-textured throughout.
b) The recommended condom should have straight and parallel sides, without constrictions and with a visible shoulder leading to a reservoir tip.
c) Shape may be modified in line with normal commercial condom designs.

If the shape is other than above, attach a dimensioned drawing with detailed description and check here.

Verify above by visual inspection.

Integral Bead

The open end of the condom shall have a rolled ring of latex called an integral bead.

Color

- The recommended condom should be translucent and without added coloring.
- If colored condoms are desired, pigments must be suitable for use in medical devices.
- If a pigment is required, indicate the color here.

Verify above by visual inspection.

Scents and Flavoring

a) The condoms shall not give off an unpleasant odor when the package is opened at any time after manufacture and for the shelf life of the product. (Condoms have a characteristic odor of rubber, which tends to dissipate quickly once the package is opened.)
b) Appropriate reference samples should be retained by the testing laboratory and can be used to resolve disputes over odor.
c) The recommended condom should be free from added fragrance and flavoring agents.
d) Users may specify the addition of a suitable fragrance or flavor to mask the characteristic rubber odor. Such fragrances and flavors must be non-toxic and non-irritating and must not degrade the rubber as demonstrated by biocompatibility studies conducted according to ISO 10993.

- If a fragrance is desired, describe here.
- If a flavor is desired, describe here.

Verify by visual inspection and smell.

Width

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

Testing: In accordance with test method in ISO 4074:2002, Annex E.

Requirement: A width of 53 mm, with a tolerance of ± 2 mm is allowed for individual condoms with a tolerance of ± 1 mm for the mean of the LOT.

- AQL 1.0
- If the width is not (53 ± 2) mm, indicate the width here.

Length

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

Testing: In accordance with test method in ISO 4074:2002, Annex D.

Requirement:

- A minimum of 170 mm for condoms with widths less than 50.0 mm. A minimum of 180 mm for condoms with widths of 50.0 mm up to 56.0 mm. A minimum of 190 mm for condoms with widths greater than 56.0 mm.
- AQL 1.0
- Other lengths may be specified based on the best available data on the target population.

Thickness

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

Testing: In accordance with test method in ISO 4074:2002, Annex F.

Requirement: The thickness measurements are taken at three points: 30 ± 5 mm from the open end, 30 ± 5 mm from the closed end (excluding the reservoir tip), and at the mid distance between those two points.

- AQL 1.0
- The mean single-wall thickness (calculated from the three individual measurements) for each condom shall be 0.065 ± 0.015 mm.

Quantity of Lubricant Including Powder

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

Testing: In accordance with test method in ISO 4074:2002, Annex C.

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.
- 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 color, print design and identification markings, including Pantone references and font sizes, shall be as specified by the buyer and attached to this specification.

- Individual packages shall be square and shall not distort the rolled condom. The package shall be hermetically sealed and shall protect the product from oxygen, ozone, water vapor, ultraviolet and visible light.
- Verify by visual inspection.
- 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.

- Alternative packaging materials can be accepted if their impermeability and strength are comparable to the recommended packaging above, or if there is real-time stability data to show the condom in its pack has adequate shelf-life.
- If an alternative material is required, attach the full specification and mark here.
- The LOT numbers on packages must be printed at the time of packaging.
- Verify by Supplier's data or independent test.

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.

Requirement: The individual package shall be individually marked as follows:

- Manufacturer's name
- LOT number of LOT identification code (printed at the time of packaging, not pre-printed)
- Manufacturing date (dip date): Month and year - labeled Manufacturing date
- Expiry date: Month and year - labeled expiry date
- Date in a language to be specified by the purchaser. AQL 2.5

4. Packaging for Shipment

Inspections or verifications in this section will generally be carried out at the pre-qualification stage and during periodic audits.

Consumer Packs

No consumer packs are included in the specification. The purchaser should specify in accordance with the requirements of the program.

Inner Boxes

a) The inner boxes shall be constructed of board plasticized on its inner surface and of sufficient strength and rigidity that the box will retain its shape through every stage of the distribution chain.
b) The inner boxes will be marked in a legible manner to show 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 purchaser. 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 purchaser. 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, expressed in millimeters
- Number of condoms in box
- Instructions for storage

Note: All markings must be legible. Can be specified in accordance with program requirements.

Exterior Shipping Cartons

a) The inner boxes shall be packed into plastic or other waterproof lining bags, which will be placed in three-walled corrugated fiberboard cartons made from weather-resistant fiberboard with a bursting test strength of not less than 1900 kPa.
b) 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 75mm-wide water-resistant tape applied to the full length of the center seams and extending over the ends not less than 75mm.
c) The cartons will be secured by plastic strapping at not less than two positions.
d) 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.
e) 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 purchaser. 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 purchaser. 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

LOT Traceability

a) To facilitate monitoring of LOT quality during shipping and storage, all exterior shipping cartons for each discrete LOT shall be assembled and shipped together.
b) 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.
c) These efforts may include the use of very large lettering for LOT codes on the exterior shipping cartons, color coding and palliating of discrete LOTS. Instructions to this effect shall be issued to shipping and warehouse personnel.

5. Registration and Certification Requirements

Certificate of Registration Status in Country of Origin

Condoms 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.

Compliance with Good Manufacturing Practices

The Supplier must be able to provide certification that the oral contraceptives are manufactured according to WHO GMPs. Such certification can be found in the WHO Certification Scheme *Certificate of a Pharmaceutical Product*. Supplier also must be able to provide copies of its annual GMP audit reports.

6. 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.

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 shipment 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 Technical Specification performed by a laboratory suitably equipped and qualified to conduct QA tests on condoms according to WHO requirements.

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[64], 33 ISWG[65]).

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 deburred, polished and free from sharp edges, for example by barrel tumbling.

2.4 Thread

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

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

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.

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[64] American Wire Gauge

[65] Imperial Standard Wire Gauge

2.6 Insertion rod

Food contact grade radiation stable ABS (Acrylonitrile-Butadiene-Styrene polymer) or food contact grade radiation stabilized polypropylene (PP) with a tip diameter of (2.6 ± 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 polymerand the thread is 3 years from the date of manufacturewhen stored at temperatures under 30 °C and 2 yearswhen stored at temperatures between 30 °C and 35 °C. The maximum storage period for the frame polymerand the thread is 3 years from the date of manufacturewhen stored at temperatures under 30 °C and 2 yearswhen stored at temperatures between 30 °C and 35 °C.

Provided the tensile strength of the frame materialexceeds 13 MPa (which may be determined by testingmoulded frames) and the breaking force of the threadexceeds 9.5 Newton, then the materials may be usedfor a further 3 years when stored at temperaturesunder 30 °C and 2 years when stored at temperaturesbetween 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 clause7.4, 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 levonorgestrela progestin and offers contraception for up to five years.
- A single-rod system that contains etonogestrela progestin and provides contraception for three years.

Materials

The two rods Levonorgestrel implants are a progestin-only product; they contain noestrogen. A set consists of two small, flexible rodsthat have a core consisting of anequal mixture of levonorgestrel andsilicone elastomer. The rods arecovered with thin-walled siliconetubing and are sealed at the endswith Silastic medical grade adhesive.Each rod is 43 millimeters (mm)long, 2.5 mm in diameter and contains75 mg Levonorgestrel **(**LNG**)**.

The single sterile rod implant is 4 cm in length with a diameter of2 mm. **It c**onsists of an ethylene vinylacetate (EVA) copolymercore, containing 68 mg of the synthetic progestin etonogestrel (ENG), surrounded by anEVA copolymer skin.The applicator consists of acrylonitrile-butadienestyrenebody 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, eachfilled with 75 mg of levonorgestrel,for use in one woman.

Thesingle rod implant containing68mg etonogestrel is preloadedin the needle of a disposable applicator. The sterile applicatorcontaining 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 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).

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** rodsLevonorgestrelimplantshould be stored away from excessiveheat (temperatures higherthan 30°C) and moisture. An unopened,undamaged sterile packof **two** rods, if properly stored,has a shelf life of 5 years. The lastdate 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 storingin 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 theexpiration date (shelf life), a setof **two** rods is effective for5 years. The rods should be removedby the end of the fifth year.If desired, a new set of rods maybe inserted in the same locationimmediately 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 largelyreplaced the older combined ECPs because they are more effective and cause fewer sideeffects. Although this therapy is commonly known as the morning-after pill, the term ismisleading; ECPs may be initiated sooner than the morning after—immediately after unprotectedintercourse—or later—for at least 120 hours after unprotected intercourse.

Progestin-only ECPs contain no estrogen. Only the progestin levonorgestrel has beenstudied for freestanding use as an emergency contraceptive. The original treatment schedulewas one 0.75 mg dose within 72 hours after unprotected intercourse, and a second 0.75 mgdose 12 hours after the first dose. However, recent studies have shown that a single dose of 1.5mg is as effective as two 0.75 mg doses 12 hours apart.[66]

The antiprogestin mifepristone has also been extensively studied for use as an emergencycontraceptive pill. Mifepristone is a firstgeneration progesterone receptor modulator. A secondgeneration antiprogestin, ulipristal acetate (30mg in a single dose), has been studied for use as emergency contraception and has been foundto be highly effective and welltolerated.[67] 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

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[66] 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 multicentrerandomised 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.

[67]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.[68]

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.[69]

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

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[68] 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.

[69] Available at: http://www.who.int/medicines/areas/quality_safety/regulation_legislation/certification/en/index.html.

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.

1.11 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 Submission Form

Date: (insert: date of bid)

IFB Number: (Purchaser specify: "IFB No.)

Contract: (insert: name of Contract)

To: (*Purchaser insert: Name and address of purchaser*)

Dear Sir or Madam:

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

(insert: amount of local currency in words)	(insert: amount of local currency in figures)
plus	
(insert: amount of foreign currency A in words)	(insert: amount of foreign currency A in figures)
(as appropriate, include the following)	
plus	
insert: amount of foreign currency B in words)	(insert: amount of foreign currency B in figures)
plus	
(insert: amount of foreign currency C in words)	(insert: amount of foreign currency C in figures)

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

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

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

We agree to abide by this bid, for the Bid Validity Period specified in clause 18.1 of the BDS and it shall remain binding upon us and may be accepted by you at any time before the expiration of that period.

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

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

Name and Address of Agent _____

_____

_____

Amount and Currency _____

Purpose of Commission or Gratuity _____

_____

(if none, state "none")

Dated this _____day of _____

(insert: number) (insert: month), (insert: year)

Signed: _____

Date_____

In the capacity of_____ (insert: title or position)

Duly authorized to sign this bid for and on behalf of:

_____ (insert: name of bidder)

Price Schedule for Contraceptives Manufactured Outside of Pakistan

(Group C Bids)

Name of Bidder: _____ IFB Number _____ Page _____ of _____

1 Product Code	2 Product	3 Strength	4 Dosage form	5 Unit Pack size	6 Qty offered	7 Unit Prices				8 Total Unit Price (a+c+d) Or (b+c+d)	9 Total Price Per Item (6 x 8)	10 Local Agent's Commission As a % of FOB price Included In Quoted price	11 Shipment Weight And volume	12 Name Of Manufacturer	13 Country Of Origin	14 Pharmacopoeial Standard
						(a) Unit Price FOB Or FCA Port or Place of loading	(b) CIF at Port of Entry Or CIP Named Place of destination (specify one)	(c) Inland Transport Insurance & other Local Costs Incidental To delivery If specified	(d) Other Incidental Costs as Defined in The SCC							

Note:

(i) Column 7(c) is optional and it will be applicable only when require in accordance with ITB clause 16.2 (b) (iv) and (v) and the related provisions in the Bid Data Sheet

(ii) For column 9, pursuant to ITB 30.1, in the case of discrepancy between unit price and total price, the unit price shall prevail

Total Bid Price: _____
Currency: _____
In figures: _____
In words: _____

Signed: _____

Dated: _____

In the capacity of: (insert: title or other appropriate designation)

Price Schedule for Domestic Contraceptives Manufactured within Pakistan

Name of Bidder: _____ **IFB Number** _____ **Page** _____ **of** _____

1 Product Code	2 Product	3 Strength	4 Dosage form	5 Unit Pack size	6 Qty offered	7 Unit Prices			8 Total Unit Price (a+b+c)	9 Total Price Per Item (6 x 8)	10 Sales And Other Taxes Payable If contract is awarded	11 Name Of Manufacturer	12 Pharmacopoeial Standard	13 Local Input in the cost as % of ex-factory price in column 7 (a)
						(a) Ex-factory Ex-warehouse Ex-showroom Off the shelf	(b) Inland Transport Insurance & other Local Costs Incidental To delivery	(c) Other Incidental Costs as Defined in The SCC						

Note:

(i) Column 7(c) is optional and it will be applicable only when require in accordance with ITB sub-clause 16.2 (a) (iii) and (iv) and the related provisions in the Bid Data Sheet

(ii) For column 9, pursuant to ITB 30.1, in the case of discrepancy between unit price and total price , the unit price shall prevail.

(iii) For column 13, a breakdown of the cost of local labour, local raw materials and local commponents provided from within the country should also be indicated separately as specified in ITB sub-clause 27.1 along with adequate proof to substantiate each of these local inputs.

Total Bid Price: _____

Currency: _____

In figures: _____

In words: _____

Signed: _____

Dated: _____

In the capacity of: (insert: title or other appropriate designation)

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.

Manufacturer's Authorization

Date: (insert: date (as day, month and year) of Bid Submission)

ICB No.: (insert: number of bidding process)

To: (insert: complete name of purchaser)
WHEREAS

We (insert: complete name of Manufacturer), who are official manufacturers of*(insert: type of contraceptives manufactured*), having factories at (*insert: full address of Manufacturer's factories*), do hereby authorize (*insert: complete name of bidder*) to submit a bid the purpose of which is to provide the following contraceptives, manufactured by us (insert: name and or brief description of the contraceptives), and to subsequently negotiate and sign the Contract.

We hereby extend our full guarantee and warranty in accordance with clause 27 of the General Conditions of Contract, with respect to the contraceptives offered by the above firm.

Signed: (*insert: signature(s) of authorized representative(s) of the Manufacturer*)

Name: (*insert: complete name(s) of authorized representative(s) of the Manufacturer*)

Title: (*insert: title*)

Duly authorized to sign this Authorization on behalf of: (*insert: complete name of bidder*)

Dated on _____day of _____, _____(*insert: date of signing*)

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 and Address of purchaser)

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)

Bid Security (Bid Bond)

(The Surety shall fill in this Bid Bond Form in accordance with the instructions indicated.)

BOND NO. _____

BY THIS BOND (*insert name of bidder*) as Principal (hereinafter called "the Principal"), and (*insert name, legal title, and address of surety*), authorized to transact business in (*insert name of country of purchaser*), as Surety (hereinafter called "the Surety"), are held and firmly bound unto (*insert name of purchaser*) as Obligee (hereinafter called "the purchaser") in the sum of (*insert amount of Bond*)[1] (*insert amount in words*), for the payment of which sum, well and truly to be made, we, the said Principal and Surety, bind ourselves, our successors and assigns, jointly and severally, firmly by these presents.

WHEREAS the Principal has submitted a written Bid to the purchaser dated _____ the day of_____ _____, 20____, for the construction of (*name of Contract*) (hereinafter called the "Bid").

NOW, THEREFORE, THE CONDITION OF THIS OBLIGATION is such that if the Principal: withdraws its Bid during the period of bid validity specified in the Form of Bid; or 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;

then the Surety undertakes to immediately pay to the purchaser up to the above amount upon receipt of the purchaser's first written demand, without the purchaser having to substantiate its demand, provided that in its demand the purchaser shall state that the demand arises from the occurrence of any of the above events, specifying which event(s) has occurred.

The Surety hereby agrees that its obligation will remain in full force and effect up to and including the date 28 days after the date of expiration of the Bid validity as stated in the Invitation to Bid or extended by the purchaser at any time prior to this date, notice of which extension(s) to the Surety being hereby waived.

IN TESTIMONY WHEREOF, the Principal and the Surety have caused these presents to be executed in their respective names this _____day of _____ 20_____

Principal: _____ Surety: _____

Corporate Seal (where appropriate)

_____ _____

(*Signature*)(*Signature*)

(*Printed name and title*) (*Printed name and title*)

[1] *The amount of the Bond shall be denominated in the currency of the purchaser's country or the equivalent amount in a freely convertible currency.*

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 purchaser)* (hereinafter called "the purchaser"), 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

dated the (*insert: number*) day of *(insert: month)*,*(insert: year)*

BETWEEN

_____

(insert: name of purchaser), "the Purchaser"

and

_____

(insert: name of Supplier), "the Supplier"

Performance Security Bank Guarantee

_____

(insert: Bank's Name, and Address of Issuing Branch or Office)

Beneficiary: _____

(insert: Name and Address of Purchaser)

Date: _____

PERFORMANCE GUARANTEE No.: _____

We have been informed that (insert: name of Supplier) (hereinafter called "the Supplier") has entered into Contract No. (*insert: reference number of the contract*) dated _____with you, for the supply of (*insert: description of goods*) (hereinafter called "the Contract").

Furthermore, we understand that, according to the conditions of the Contract, a performance guarantee is required.

At the request of the Supplier, 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*)[1] upon receipt by us of your first demand in writing accompanied by a written statement stating that the Supplier is in breach of its obligation(s) under the Contract, without your needing to prove or to show grounds for your demand or the sum specified therein.

This guarantee shall expire no later than the __day of __, 20_____,[2] and any demand for payment under it must be received by us at this office on or before that date.

This guarantee is subject to the Uniform Rules for Demand Guarantees, ICC Publication No. 458, except that subparagraph (ii) of Sub-article 20(a) is hereby excluded.

_____

(signature(s))

---

1 The Guarantor shall insert an amount representing the percentage of the Contract Price specified in the Contract and denominated either in the currency(ies) of the Contract or a freely convertible currency

2 Established in accordance with clause 8.4 of the General Conditions of Contract ("GCC"), taking into account any warranty obligations of the Supplier under clause 15.2 of the GCC intended to be secured by a partial performance guarantee. The purchaser should note that in the event of an extension of the time to perform the Contract, the purchaser would need to request an extension of this guarantee from the Guarantor. Such request must be in writing and must be made prior to the expiration date established in the guarantee. In preparing this guarantee, the purchaser might consider adding the following text to the form, at the end of the penultimate paragraph: "The Guarantor agrees to a one-time extension of this guarantee for a period not to exceed (six months) (one year), in response to the purchaser's written request for such extension, such request to be presented to the Guarantor before the expiry of the guarantee."

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.

Additionalsheetsshouldbeappended,asnecessary,toaccommodateremarksand 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 4: 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 causestockouts.

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 impacton the overall effectiveness and efficiency of the RH supply process, either favorably or unfavorably, depending on the decisions they make:

- Draftingand 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., routinerotations 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, whichattract 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
- addnew products to the essential medicines list

- select the procurement option; e.g., procurement handled directly by staff orindirectly 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.[70]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

[70]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.

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, 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.[71]

[71]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.

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, 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 processhas 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**
I. 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
- arethebenchmarksagainstwhichthepurchaserwilljudgethetechnical 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.[72]

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
- levelthe 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.

e. Procurement Requisition

[72]For more information, see http://www.gavialliance.org/support/who/index.php

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*[73] 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).

[73]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/.

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 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

a. Accounting system not showing outstanding commitments
   - *Significance:* Overstated line item balances.
   - *The result:* Some managers will use funds that will be needed later.

b. 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.

c. 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.

d. 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.

e. 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.

f. 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

a. 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.

b. 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.

c. 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.

d. 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.

e. 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.

f. 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

a. 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.

b. 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.

c. 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 correctioncostly; L/C may not be useful to ensure product quality.

d. 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.

e. 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

a. 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.

b. 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.

c. 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.

d. 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

a. 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.

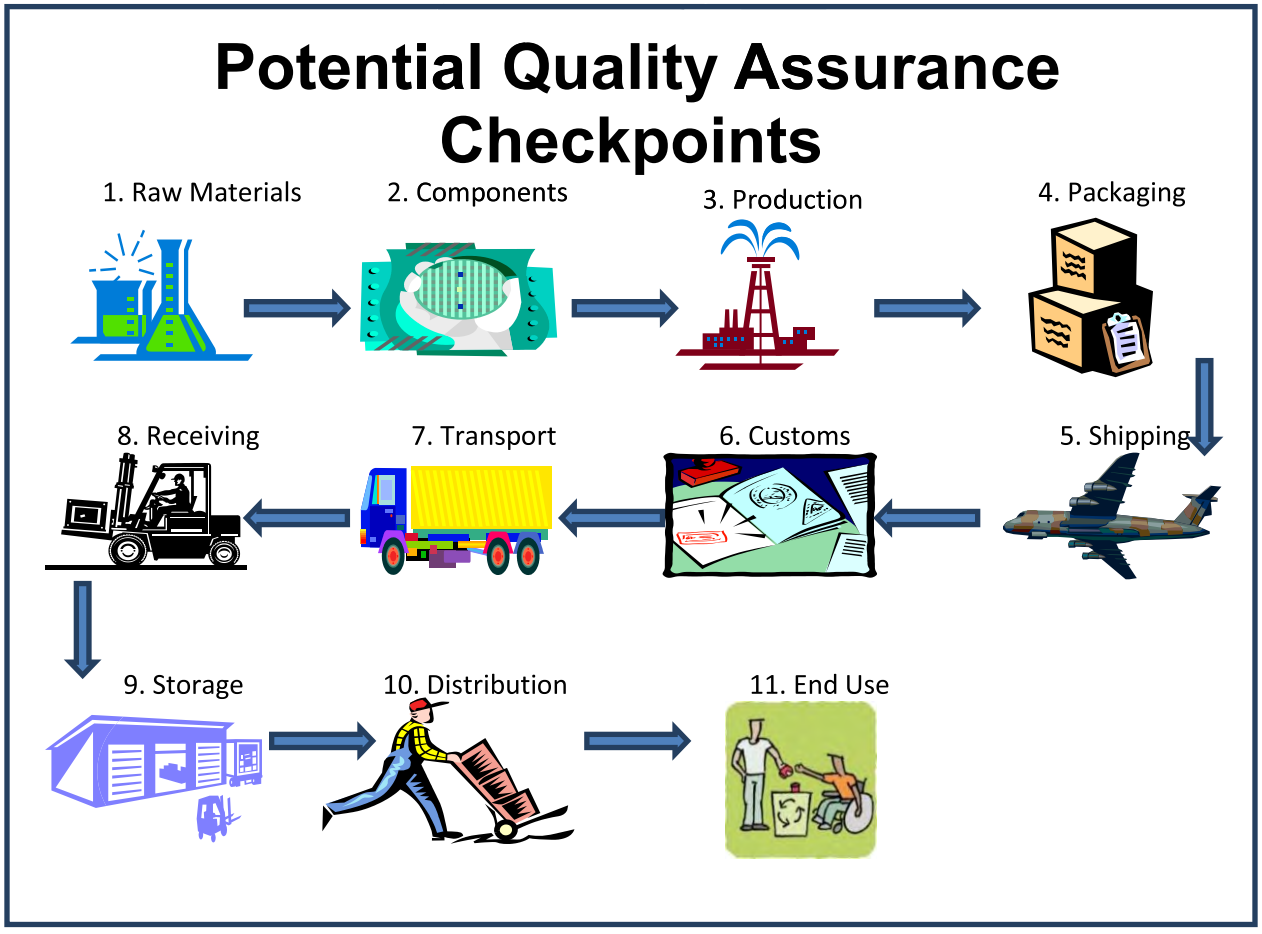
9. Contract performance and monitoring

- 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 5: 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 appendix6: 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 6: 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'sPrequalification 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.74
- **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

[74]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/.

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 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).[75]

[75]Also see the "*Bidder Information Form" in the World Bank's Standard Bidding Document: Procurement of Health Sector Goods*

Appendix 7: 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[76] from each manufacturing lot (usually 200–315 samples).
Oral contraceptives andemergency 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

[76]The Male Latex Condom - Specification and Guidelines for Condom Procurement

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 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 SocieteGenerale 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.[77]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).

A *normal* inspection can be changed to *reduced* (less strict) level (tables IIC or IIIC), if the following requirements are met:

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[77]The WHO model condom specification uses G-1 for performance requirements, S-2 for design requirements and S-3 for packaging requirements

- 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 laboratoryshould 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 haswording 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 injectablecontraceptives 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[78] or its contents is damaged.
- 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.

[78]Blister pack, ampoule

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 boxcondition/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 productwithin 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 boxcondition/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 productwithin 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 deviceregistration 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 boxcondition/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-dermalImplants

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 productwithin 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 deviceregistration 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-dermalImplants (*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 boxcondition/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 productwithin 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 boxcondition/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	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	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	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇧	⇩	⇩	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	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇧	⇩	⇩	2 3	3 4	5 6	6 7	8 9	10 11	⇧	⇧	⇧	⇧	⇧	⇧	⇧							
K	50	⇩	⇩	⇩	⇩	⇩	⇩	⇧	⇩	⇩	⇩	2 3	3 4	5 6	6 7	8 9	10 11	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧							
L	80	⇩	⇩	⇩	⇩	⇩	⇧	⇩	⇩	⇩	⇩	3 4	5 6	6 7	8 9	10 11	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧							
M	125	⇩	⇩	⇩	⇩	⇧	⇩	⇩	⇩	⇩	4 5	5 6	6 7	8 9	10 11	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧							
N	200	⇩	⇩	⇩	⇧	⇩	⇩	⇩	⇩	⇩	6 7	7 8	8 9	10 11	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧							
P	315	⇩	⇩	⇧	⇩	⇩	⇩	⇩	⇩	⇩	8 9	9 10	10 11	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧							
Q	500	⇩	⇧	⇧	⇩	⇩	⇩	⇩	⇩	⇩	10 11	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧							
R	800	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧							

⇩ = 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	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								1 2	3 4	4 5	5 6	7 8	10 11	12 13													
N	First	125	125		⇩	*	⇧	⇩	⇩	0 2	0 3	1 3	2 4	3 6	4 7	5 9	⇧													
	Second	125	250							1 2	3 4	4 5	5 6	7 8	10 11	12 13														
P	First	200	200	⇩	*	⇧	⇩	⇩	0 2	0 3	1 3	2 4	3 6	4 7	5 9	⇧														
	Second	200	400						1 2	3 4	4 5	5 6	7 8	10 11	12 13															
Q	First	315	315	*	⇧	⇧	⇩	0 2	0 3	1 3	2 4	3 6	4 7	5 9	⇧															
	Second	315	630					1 2	3 4	4 5	5 6	7 8	10 11	12 13																
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 8: Endorsement of Manual by SPPRA, Sindh

No. Dir(Enf-I)/SPPRA/USAID/13-14/ 4039
GOVERNMENT OF SINDH
SINDH PUBLIC PROCUREMENT REGULATORY AUTHORITY
Karachi, dated the 30th January, 2014

To,

Dr. Muhammad Tariq,
Country Director,
USAID Delivery Project
Islamabad.

SUBJECT: CONSULTATION ON CONTRACEPTIVE PROCUREMENT MANUAL FOR HEALTH AND POPULATION DEPARTMENTS OF SINDH

Please refer to your letter dated 07.01.2014. The Authority has examined the subject Procurement Manual prepared for Department of Health and Population Welfare Department, Government of Sindh and to inform that the observations of the Authority have been incorporated in the Manual and the Manual is endorsed.

2. SPPRA appreciates the efforts put in by the USAID Deliver Project and hopes to continue a productive collaboration.

(IFFAT MALIK)
Director (Enforcement-I)

Copy for information:

1. Mr. Inamullah Khan, Director, Field Operation & LMIS, USAID | DELIVER PROJECT, Islamabad.
2. Dr. Mumtaz Brohi, Technical Advisor, USAID | DELIVER PROJECT, Islamabad.
3. Dr. Tanweer Hussain, Sr. Provincial Logistics Managers, USAID | DELIVER PROJECT, Islamabad.

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 L/Cs.
accrued	Accumulated through growth, over time; for example, accrued penalties, accrued income.
acceptable quality level (AQL)	A termused in quality assurance to classify defects into critical, and major and minor categories.
advising bank	In documentary credits (L/Cs) and commercial bank that notifies a beneficiary and/or transmits documents without taking on financial obligation.
agent	A supply term for an independent contract or authorized by a manufacturer to promote and sell the manufacturer's products, within a designated geographic area. Often an agent will represents ever al 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 isloadedon board an aircraft; and includes a description of the commodity being shipped, shipping instructions, terms and conditions of the shipment, and applicable transportation charges.
applicant	A legaltermused in banking to describe a party (usually, the buyer) who is asking the bank to issue a commercial L/Cs in favor of a specified beneficiary (usually, the seller). After the L/C has been issued, the *applicant* becomes the *accountee*.
arbitration	To avoid costly and lengthy litigation, this helps resolved disagreements between two or more parties; impartial individuals, called arbitrators, manage the process. The ICC maintains a court of arbitration, as do many individual countries.
authorized person	Any person who is granted the power to authorize a transaction or other wise make a commitment on behalf of a procuring agency.

award notification	Notification from the purchaser to the successful bidder recommended for a contract; usually 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.*
beneficiary	A legal banking term that describes the party who is entitled to collect funds guaranteed by a commercial L/Cs, on presentation of specific 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; the intending purchaser specifies the requirements.
bidding documents	A written description and set of terms and conditions of an intended purchase that an intending buyer circulates to prospective sellers.
bid offer	A procurement term that means an offer for goods or services submitted or received in response to a specific invitation to bid.
Bid EvaluationCommittee	A committee established by an authorized person, or by the federal procurement cell, of a ministry to evaluate bids and quotations for procurement.
Bid OpeningCommittee	A committee established by an authorized person, or by the federal procurement cell of a ministry, to open bids and quotations for procurement.
bid security	A financial instrument 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 includes 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	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 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, coming from abroad, from port and customs authority.
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 were 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 the 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 excess 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 to achieve an improper purpose, including to improperly influence 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 describes the goods, the agreed-to 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. Several types of competitive bidding procedures include International Competitive Bidding, Local Competitive Bidding, Limited Competitive Bidding, and Request for Quotation.
conditional discount; cross discount	A discount sometimes offered by potential suppliers bidding on two or more contracts, simultaneously; this would only apply if the supplier was awarded two or more contracts.

consignee	A term used in shipping that describes the party to whom entrusted with something; 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 or market context.
Contract	An agreement entered into by two parties to execute a certain activity; e.g., sale and purchase, construction, providing services, etc.
contractor	A party who has entered into a contract with a purchaser to supply certain goods, or perform certain works, or provide certain services.
convertible currency	Currency that can be quickly bought and sold for other currencies; commonly traded internationally.
correspondent relationship	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 improperly influence the actions of another party.
Coverage	Health sector program term for the estimated number of individuals actually served, as a percentage of the target population.
Criteria	Specific points, standards, qualities, or 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 to evaluate a product's appearance, packaging, and packing using visual examination and comparison with a precise description of requirements; results in a classification of any defects, based on importance. There are published standards for how many defects can be allowed in a particular lot size under different assumptions.
defect, critical	A defect that, based on professional criteria, makes a product dangerous or not viable for its intended use.

defect, major	A defect that could 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 credit for development programs of the government; for 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 instead of through UNICEF or another third party.
discrepancies	Used in banking and trade to mean lack of agreement with stated requirements and/or documents.
Documentaryevidence	Being, consisting of, or contained exclusively in documents.
domestic preference allowance	Term used in World Bank procurement documents to describe a competitive advantage, expressed as a percentage, which is sometimes given to local manufacturers of goods competing for contracts against international sources.
drug formulary	Sub-set of *essential drugs* keyed to specific levels of health care (facility).
duties	Tax charged by a government, especially for imports.
eligibility (criteria)	Not excluded from competing for contracts, in general, because of nationality, debarment, lack of regulatory approval, etc.

entity	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	Bid that meets the basic eligibility criteria, after a preliminary screening, and that 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)	Model list of around 300 drugs that the majority of the population require for their health needs.
estimate of procurementrequirements	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	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	Supply term for a date established by the manufacturer that is displayed 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	Legal document that conveys financial commitment, such as a bond.
financial powers	Authority given to an officer to spend in the performance of his duties. In most government systems, the amount of expenditure an officer can authorize is usually related to the level of his responsibility, as well as his seniority.
forecast	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	Event or effect 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 the United Nations publication, *Development Business,* about scope of anticipated ICB procurement; which will 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)	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 that follows GMP 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 they should default on a loan or other financial obligation.
Harmonized Tariff System (HTS) Code	An international codification of merchandise for 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.
Implementationreqmt.	Defined procedures and milestones associated with a project.
implementing agency	Agency responsible for carrying out project activities and monitoring progress toward defined milestones, goals, and objectives.
Incoterms	International rules for the interpreting the most commonly used terms in foreign trade; published by the 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 inspect certain goods works or services.
inspection criteria	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).
InternationalChamber ofCommerce (ICC)	A nongovernmental organization that serves world business by harmonizing trade practices, formulating terminology, and establishing guidelines for importers and exporters.
InternationalCompetitive 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 and contractual and financial merit; awards go to the supplier making the most advantageous and cost-effective offer. All bids are final and no negotiation is allowed, except for minor contractual points, after selection of a winning bid. The ICB provides all eligible prospective bidders with an equal opportunity to participate in the competition; also known as open or unrestricted, bidding
Internationalshopping	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	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 into 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	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	Written expression of the purchaser made to the supplier to issue an award in favor of the supplier.

letter of credit (L/C)	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 prove their performance.
licensed product	For pharmaceuticals, vaccines, and contraceptives, licensing by the regulatory authority of both the importing and exporting country implies a quality standard based on verified GMPs, quality assurance data, and appropriate oversight.
liquidated damages (L/D)	In sales contracts, specified sum to be paid to the purchaser if the seller defaults on its obligation (usually pertaining to a delivery schedule).
Limited InternationalBidding (LIB)	Procurement term describing the bidding process that limits participation to international and domestic suppliers that the purchaser has pre-qualified, pre-selected, or short-listed in some way. See *restricted bid* and *pre-qualification*.
lot	Supply term that can be used in two ways: production lot (see batch-manufacturing) and shipping lot.
lot or batch number	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 that has received exactly 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 another way, and was found to conform to the regulations of the country of manufacture and is released for sale. In some cases, this document is titled "Certificate of Free Sale."
lowest evaluated bid	A bid (1) most closely conforms to the evaluation criteria and other conditions specified in the bidding document, and (2) has the lowest evaluated cost.
manufacturer'srepresentative	A direct employee of a manufacturer who is responsible for promoting the use of, provides information about, and sells the manufacturer's products. In some cases, the representative also facilitates importation. Sometimes, the term *agent* is used for the same relationship.

margin of preference	See *domestic preference*.
marking	Used in packing and shipping for applying 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 that limits in any way the responsibilities, duties, or liabilities of the bidder or any rights of the purchaser.
merit point system	Numerical system used to evaluate and compare offers or bids. Points (based on a total of 100) are assigned based on 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	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)	Procurement method that follows the same format as International Competitive Bidding, but is 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 in the native language or in another language.
National Regulatory Authority (NRA)	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 the title to the goods has been transferred to a new owner by delivery; usually

	requires transfer of funds from buyer to seller, as well.
negotiable shipping document	Document that establishes ownership of goods and, therefore, has monetary value; usually, an ocean bill of lading.
nongovernmental 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 includes such critical items as signatures, bid security, completeness, agreement to terms, and conditions, etc.
No Objection Certificate	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 ObjectionDetermination	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, or concealing of evidence material to the investigation; or, making false statements to investigators that would materially impede an investigation into allegations.
offer	Used interchangeably with *bid* and *proposal*.
open bid	Formal procurement procedure in which bids for a required product are accepted from any interested local or international source.
packaging	A product's primary containers and coverings. For injectables, vials and ampoules are the primary packaging; boxes and bags containing several, up to 100, vials or ampoules are secondary packaging. For tablets, blister packs or tins may be the primary packaging.
packaging for bidding	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.
Packingrequirements	Identifies how products should be packed to withstand the handling and climatic conditions 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 the inclusion of cold chain monitoring devices.
packing list	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, 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. U.S. drug patents are usually good for 17 years.
payment terms	Description of how, where, and when payment will be made; for example, L/C, cash in advance, open account.
performance security	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	Book published, usually under the jurisdiction of the government, that contains 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	Port (including airport and land-port) designated in the bid, and specified in the bill of lading or air waybill (AWB), where the consignment(s) under a contract is (are) to be carried to.
port of loading	Port (including airport and land-port) designated in the bid and specified 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)	Process of pre-approving suppliers for participation in bids, based on a judgment of reliability, technical competence, and financial stability.
pre-qualification (of product)	Process of pre-determining that a specific product (usually a pharmaceutical or vaccine) of a specific manufacturer meets stated requirements and can be considered for purchase contracts in the approving country. Licensing by the NRA in the purchasing country automatically confers pre-qualification status.
pre-shipmentinspection	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 on.
procurement	Formal process of acquiring goods, works, or services.
procurement agent	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, and source of funds; time period during which goods will be procured, and the method of procurement; separate from *operational plan*.
Procurementrequirements	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.
Procurementtransaction	Agreements and actions of a buyer and a seller around a specific purchase; usually documented and legally binding.
procurement unit	Officer or team designated by a procuring agency to conduct procurement on its behalf.
procuring agency	Program with responsibility to undertake procurement.
performa invoice	Abbreviated invoice prepared by a supplier in advance of a sale or shipment. Closely approximates the weight and value of the shipment and other relevant data. 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	Procurement term that describes an offer to supply goods or services 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	Term that describes 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	Autonomous body responsible for prescribing regulations and procedures for public procurements by the provincial government-owned public sector organizations to improve governance, management, transparency, accountability, and quality of public procurement of goods, works, and services.
public sector supply service	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	Term used in distribution systems to indicate that peripheral levels request deliveries of specific kinds and amounts from a central level.
procurement office	Offices that will undertake and accomplish the task of procurement of goods under the HPSP.
push system	Term used in distribution systems to indicate that a central authority is sending goods to lower levels, based on its own calculations of need instead of specific requests from the lower levels; i.e., it *pushes* goods to the lower levels.
qualification (criteria)	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 (QA)	Combination of organized activities 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 the manufacturing organization provides confidence to the purchaser. In the context of pharmaceuticals, vaccines, and contraceptives, it is typically done before a shipment leaves the manufacturer's facility and/or before the product is released for use in a country.

quality control (QC)	Manufacturing term that describes internal operational techniques and activities that monitor the manufacturing process and eliminate the causes of unsatisfactory performance. Some QC and QA actions are interrelated.
registration	Term used in regulating pharmaceuticals and vaccines; exact usage varies from country to country. It is often synonymous with licensing but it can mean that the particulars about a shipment are recorded as it enters a country.
request for proposal	The term commonly used for bidding documents when procuring consultancy services.
responsive bid	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	Certain percentage of the bill money payable to a contractor for the contracted goods works or services, which is held back and retained by the purchaser, and paid after the contractor fulfills certain obligations.
revenue funds, budget	Funds, budget derived from a government's own activities (usually tax collection) instead of from development loans or grants, such as HNPSP.
safeguard	Protect, guard, and keep safe.
sampling	Process of selecting a small, representative quantity of materials from a much larger batch, shipment, or consignment. Inspecting this representative sample allows judgment about the quality of the entire batch or shipment of products without inspecting each individual unit.
schedule of requirements	Part of a bidding document that describes the quantity of goods and expected delivery time.
sealed bids	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,

	and 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	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 is not always the supplier of the goods.
shelf life	Length of time designated by the manufacturer that a product can 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; the drugs must be discarded and destroyed.
shipping marks	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 to ensure the purchaser's goods can be easily seen and identified; usually this is instructed in the bidding document.
shipping terms	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.
sole source	Procurement term that describes purchasing from a single manufacturer without competition among potential suppliers; usually applies to items that are not available from any other source. Also, see *direct procurement*.
solicitation	Procurement term for the process of inviting bids or requesting proposals for the supply of a product or service; also, refers to the document requesting bids or proposals.
specification	Detailed, precise written description.
specification committee	Committee formed by an authorized person, relevant authority or a federal procurement cell to prepare specifications and documents for procurement.
standard	Something established by authority as a rule to measure a quantity, weight, extent, value, or quality. For example, the ISO establishes *rules* for the vial closures commonly used for injectables.
substantially responsive	In World Bank procurement, a bid that contains no material

	deviations from or reservations to the terms, conditions, and specifications in the bidding documents.
supplier	Party who transfers goods out of his own control to a named recipient.
surety	Person or firm that is legally responsible for the debt, default, or delinquency of another.
survey report	Report of the insurance survey.
target population	Program term for the total number of intended clients, based on expected coverage rates.
technical evaluation committee	Committee established to assist a procurement unit, committee relevant authority, bid evaluation committee, or a federal procurement cell to review and technically evaluate documents.
threshold level	Threshold is a point of entry or beginning. In World Bank terminology, it is a monetary level that determines whether the World Bank should review a particular contract, prior to being invited and executed; and which government committee is responsible for bid evaluation. These levels are set in the loan or a development credit agreement.
trademark	Name, symbol, figure, letter, word, or mark adopted and used by a manufacturer or merchant 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 ensure exclusive use by their owners.
transparency	Openness and accountability in all activities and actions concerned with procurement.
turnover	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	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 ICC.
unresponsive bid	Procurement term used to 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)	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	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; is usually part of the contract.

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