STANDARD OPERATING PROCEDURES

PUBLIC PROCUREMENT DEPARTMENT

PROJECT MANAGEMENT UNIT
Primary & Secondary Healthcare Department

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REVISION SHEET

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1. Abbreviations

1	**DHQ**	District Headquarter
2	**THQ**	Tehsil Headquarter
3	**RP**	Revamping Project
4	**P&SHD**	Primary & Secondary Healthcare Department
5	**PU**	Procurement Unit
6	**HCE**	Healthcare Establishments
7	**MSDS**	Minimum Service Delivery Standards
8	**PPRA**	Punjab Procurement Regulatory Authority
9	**SOP'S**	Standard Operating Procedures
10	**P&D**	Planning & Development
11	**NCB**	National Competitive Bidding
12	**ICB**	International competitive bidding
13	**PQB**	Pre-Qualification of Bidders
14	**OCB**	Open Competitive Bidding
15	**DC**	Direct Contracting
16	**NT**	Negotiated Tendering
17	**SBD**	Standard Bidding Documents
18	**NHF**	National Health Fund
19	**QA**	Quality Assurance
20	**QC**	Quality Control
21	**NRA**	National Regulatory Authority
22	**GMP**	Good Manufacturing Products
23	**INCOTERMS**	International Commercial Terms (for International Procurement)
24	**EXW**	Ex-Works
25	**CIP**	Cost Insurance Paid
26	**FOB**	Free On Board
27	**ICC**	International Chamber of Commerce
28	**LC**	Letter of Credit
29	**IFB**	Invitation For Bids

30	**ITB**	Instructions to Bidders
31	**BDS**	Bid Data Sheet
32	**ADB**	Asian Development Bank
33	**UNICEF**	United Nations International Children's Emergency Fund
34	**UNFPA**	United Nation Population Fund
35	**GCC**	General Condition of Contract
36	**SCC**	Special Condition of Contract
37	**LD**	Late Delivery
38	**DRAP**	Drug Regulatory Authority of Pakistan
39	**B/L**	Bill Of Lading
40	**SBEF**	Standard Bid Evaluation Form
41	**AAT**	Advance Acceptance Of Tender
42	**LCA**	Letter Of Credit Authorization
43	**ETA**	Estimated Time of Arrival
44	**AWB**	Airway Bill
45	**VAT**	Value Added Taxes
46	**L/D**	Liquidated Damages
47	**GOP**	Government of Punjab
48	**RFQs**	Requests for Quotations
49	**DC**	Direct Contracting

2. Preface

This manual will provide guidelines and structural procedures to help the concerned officials work efficiently for the sake of enhancing overall organizational performance in DHQ and THQ Hospitals of Punjab in accordance with the Revamping Project executed by Project Management Unit (PMU), Primary and Secondary Healthcare Department (P&SHD) Government of Punjab. To perform the assigned duties efficiently and effectively, the employees should have proper understanding of the relevant concepts and have apt knowledge of the rules and regulations. They should be oriented towards the well-being of the organization and be trained in specific portfolios. This manual is, therefore, relevant for the officials serving on non-clinical assignments.

The role of Procurement Unit in Healthcare Establishment (HCE) is one of the core functions of healthcare management /administration. Good hospital management can often be a difference between a hospital with improved service delivery and the facility where the quality of patient care suffers. The mission of the revamping project is to improve quality of healthcare services at HCEs in accordance with the Minimum Service Delivery Standards (MSDS) for 125 hospitals including DHQ and THQ Hospitals of Punjab.

The pivotal role of this manual is to clarify that efficient delivery of relevant core functions is the direct responsibility of the Procurement Department of the concerned healthcare facility under the rules and regulations of Public Procurement Regulatory Authority (PPRA).

3. Scope

Most HCEs have a three-tier leadership grid; the governing body, senior managers and organized medical staff. They form a team that works together to deliver safe and high quality care. The leadership standards not only address topics such as creating a culture that fosters safety as a priority, ensuring the availability of the required number of human resource necessary to provide care, ensuring the availability of competent healthcare professionals and other caregivers, and devising and implementing a competent, efficient and effective procurement mechanism for the provision of all essential equipment's, goods and services.

This manual gives an overview of key procurement rules and regulations (in accordance with the Punjab Procurement Regulatory Authority PPRA) within P&SHD by providing understanding of the concepts, and roadmap for implementation of transparent procurement mechanism within the HCE.

4. PROCUREMENT BASICS

10.1 Historical Background

Historically, the traditional procurement practice in Punjab is administered under multiple rules, codes, manuals and instructions, some of which are:

4.1.1 Purchase Manual

It is used to provide details on procurement procedures (ranging from procurement planning to contracts of procurement of goods but not services), roles and responsibilities of procuring officials, and standard Annexures / forms to be used in the procurement process. The Purchase Manual did not cover procurements of specialized nature, such as capital works etc. Purchase Manual has been repealed vide letter No. MD. PPRA/1-1/2009 (***ANNEX-01***).

4.1.2 Buildings & Roads Code

Pertains to the matters of procurement procedures for civil works of Public Works Departments in Punjab like Irrigation, Energy, Communication & Works and Public Health Engineering Departments. The code defines the scope of the administrative and executive functions of the officers of the Buildings and Roads Department, such rulings are necessary in the interest of provincial finance and control. These departments follow their own Annexures for procurement procedures, such as solicitation documents and contract forms / terms, to the extent they are consistent with Punjab Procurement Rules, 2009.

4.1.3 Delegation of Financial Powers Rules

Includes references to procurement related functions e.g. procuring powers of government officials of various categories, mainly covers the local / insignificant purchase process.

4.1.4 Consultant Selection Guidelines

Planning & Development Department earlier issued guidelines for hiring consultants for supervision and execution of development projects. Consulting services shall be procured under Punjab Procurement Rules read with Planning and Development Consultant Selection Guidelines, 2006 and Handbook for Consultant Selection 2010. Procurements in the projects that are funded by the multilateral and bilateral partners shall be governed by the agreement between the respective donor agency and the Government of Punjab or/and Economic Affairs Division, Government of Pakistan.

10.2 Punjab Procurement Rules 2009

The Punjab Procurement Regulatory Ordinance was promulgated in 2007 to establish the Punjab Procurement Regulatory Authority. Thereafter, Punjab Procurement Rules 2009 were framed and implemented under section 26 of the Punjab Procurement Regulatory Ordinance 2007.

5. Punjab Procurement Rules 2009

The Punjab Procurement Regulatory Ordinance was promulgated in 2007 to establish the Punjab Procurement Regulatory Authority. Thereafter, Punjab Procurement Rules 2009 (***ANNEX-01***) were framed and implemented under section 26 of the Punjab Procurement Regulatory Ordinance 2007. These Rules are applicable to

a. A Department or office of the Government
b. A District Government
c. An authority, corporation, program, project, body or organization established by or under a Provincial law or which is owned or controlled by Government of the Punjab.

10.1 Purpose of the SOPs

As Punjab Procurement Rules, 2009 are exclusively focused on solicitation procedures of procurement and do not address issues such as powers of the procuring officials and provide insufficient details and actual steps to be taken by the procuring entities; hence there is need to have elaborate SOPs for guidance of such officials and entities.

These SOPs have been developed in light of the Punjab Procurement Rules 2009 (Amended), P&D Consultant Selection Guidelines 2006 to established best practices in procurement. SOPs attempts to outline:

a. Methodology/guidelines for procurement staff to undertake different steps in procurement process.
b. Roles and responsibilities of different officials. Defining roles and responsibilities of the officials involved in the procurement process is likely to improve transparency and accountability and bring about uniformity in procurement transactions.

10.2 Guiding Principles for Procurement

It is important that while applying these SOPs should consider the following principles of procurement as the guiding force, which have been laid down in Rule 4 of Punjab Procurement Rules 2009 (Amended): (***ANNEX-01***).

a. Transparency
b. Efficiency
c. Fairness
d. Economy
e. Value for money

10.3 Financial Authority

The financial authorities shall continue to be exercised under "The Punjab Delegation of Financial Powers Rules, 2006" (***ANNEX-02***). Signing of contracts and contract management shall be done by the officials as per the financial authorities delegated therein.

10.4 Principles of Competitive Bidding

5.4.1 Designing of Bids requirements.

Design the bid requirements in a way which should attract the interest of both large and small foreign and domestic suppliers. While partial bids may also be acceptable.

5.4.2 Response Time

National Competitive Bidding (NCB) allows bidders to submit offers within 15 days at least. International Competitive Bidding (ICB) allows bidders to submit offers within 30 days at least. (Rule-14 of PPR-2014) (***ANNEX-01***).

5.4.3 Non-Discrimination

Invite bids from as many foreign and domestic suppliers as possible using open advertising in newspapers, trade journals and websites; in accordance with procurement methods defined by the Punjab Public Procurement (Rule 12 PPR-2014) (***ANNEX-01***).

5.4.4 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.

5.4.5 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 catalogue number must be used. (Rule-10 of PPR 2014) (***ANNEX-01***).

5.4.6 Formality

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

5.4.7 Confidentiality

Do not open the bids before the assigned date and time. Restrict all bid information to authorized parties.

5.4.8 Transparency

Evaluate all bids against the same criteria and the terms and conditions set forth in the bidding documents (Rule 32 of PPR 2014 (***ANNEX-01***). 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 33 of PPR 2014(***ANNEX-01***).

5.4.9 Objectivity

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

5.4.10 Non-Negotiation before Award

Obtain the lowest responsible offer from each bidder through the competitive bidding process. (Rule 57 of PPR, 2014) (***ANNEX-01***).

10.5 Procurement Policy Guidelines

The Government of Punjab has established clear procurement rules (PPR-2014) that offer general guidance to personnel procuring goods and services for public sector organizations, including health. These guidelines include general principles, such as evaluation of bids based on the best value for money as opposed to lowest price, and preference for Pakistani suppliers as per government policy. The complete set of procurement rules are in appendix, which contain the PPR 2014. In addition, the latest information can be found on the PPRA website at http://ppra.punjab.gov.pk.

10.6 Procurement Methods - Goods

The Government of Punjab, when purchasing entities, requires that the most appropriate method of procurement be used for a specific purpose. The GOP procurement methods align with traditional public sector procurement practices as the estimated value of future contract increases, more stringent and documented procurement methods are required. For example, for procurement with estimated value of less than 75,000 rupee simplified petty purchase procedures can be followed, but for procurement with an estimated cost equivalent to PKR 200,000 at least three quotation would be required for any kind of Procurement within the limit as mentioned above. While procuring agency shall advertise procurement of more than [two] hundred thousand rupees up to the limit of [three] million rupees on the website of the Authority in the format specified by regulations but if deemed in public interest, the procuring agency may also advertise the procurement in at least one national daily newspaper. Any procurement exceeding three million rupees shall be advertised on the website of the Authority, the website of the procuring agency, if any, and in at least two national daily newspapers of wide circulation, one in English and one in Urdu as per PPRA Rule 12 (Subject to Rule 13 (EXCEPTION in case of Emergency) and the documented competitive bidding procedure is the default method of procurement {Rule 23, 59 (b)}. 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 procurement of medicines and supplies are as follow:

5.6.1 International Competitive Bidding

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 PPRA website, the procuring agency's website and through other internationally recognized procurement advertisement websites. All suppliers are invited to participate in the bidding process. {Rule 14 (1) of PPR 2014} (***ANNEX-01***).

5.6.2 Pre-Qualification of Bidders (PQB)

Rule 16 of PPR 2014 allows for the prequalification of suppliers in case of services, civil works and turnkey projects. Moreover, 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. Pre-qualification 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 it is for ICB.

Procedure for pre-qualification of potential bidders is described in Rules 16-17 of the Punjab Procurement Rules 2014 (***ANNEX-01***).

5.6.3 Open Competitive Bidding (OCB)

This is open, unrestricted, and is usually for national sources only. It is based on the PPR 2014; procedures are described in Rule 24-38 of PPR 2014 (***ANNEX-01***).

5.6.4 Request for Quotation

Rule 59(b) of PPR 2014 allows Requests for Quotations (RFQs) to be issued for procurement actions that are less than 200,000 Rupees and above the financial limit prescribed for petty purchases. With this method, quotations are requested and received from a limited number of suppliers, but not less than three. The quoted price and the contents are compared, and the contract is awarded based on the lowest evaluated cost.

5.6.5 Direct Contracting (DC)

With Direct Contracting (DC), price and terms are agreed to with one chosen supplier,

5.6.6 Petty Purchases

Petty purchases mean purchasing without asking others for bids (e.g., without competition). Rule 59(c) of PPR 2014, however, 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, however, is required. This method is allowed by Rule 59(a) of PPR-2014 for goods with a value of less than 75,000 (seventy five thousand rupees) rupee. Petty purchases are exempted from the requirements of bidding or quotation of prices.

5.6.7 Negotiated Tendering (NT)

This method of procurement is allowed by rule 59 (d) PPR 2014 for goods and services. This method allows tendering with one or more contractors with or without publication of a procurement notification. This method is used under limited circumstances, such as when the supplies involved are manufactured purely for the purpose of supporting a specific piece of research or an experiment, or for technical or artistic reasons connected with protection of exclusive rights or intellectual property, the supplies may be manufactured only by a particular supplier, or for reasons of extreme urgency. (Rule 59(d) of PPR 2014).

10.7 Rules and Tools for Procurement of Goods

5.7.1 Rules for Procurement of Goods

a. Punjab Procurement Rules 2014

PPRA, Government of Punjab has developed and adopted a set of procurement rules titled "Punjab Procurement Rules 2014" which are based on widely acknowledged principles of good public procurement practice. These rules are applicable to all procurement involving public funds, subject to one exception-if the regulations conflict with an international obligation or agreement, the provisions of that agreement prevail. PPR-2014 covers the organization of public procurement, basic procurement rules and choice of procurement methods. Procurement detail is based on National Open Competitive Bidding. In addition, Rule 67 of PPR-2014 describes the process for complaints and appeals.

5.7.2 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 3 for a copy of the Drug Rules 1986 (***ANNEX-03***).

a. **Tools for Procurement of Goods/Drugs/Medicine**

The main tools applicable to procurement of goods are the Standard Bidding Documents (SBD) used by Government of Punjab departments and those offered by the World Bank (***ANNEX-04***).

b. **Government of Punjab Standard Bidding Documents**

The Primary and secondary Healthcare Department Punjab developed standard bidding documents for use in national Open Competitive Bidding (***ANNEX-05***).

All relevant tools for procuring 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.

10.8 Procurement Plan

When procuring entities, Rule 8 of PPR-2014 requires that an annual (or annually updated, project-wise) procurement plan be submitted for approval before any procurement can take place. The procurement plan includes a broad description of the commodities to be purchased, a budget amount and source of the budget, a time frame when goods will be procured, and the method of procurement.

10.9 Quality Assurance (QA)

a. This manual focuses on procurement of quality commodities. The quality of the products, goods, services, and works is an important component of an overall approach to quality of care within the departmental projects. The consequences of poor quality products include lack of therapeutic effect, as well as possible adverse health consequences. For these reasons, ensuring the quality of goods and 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 starts from development of a specific product to its usage by the end user.

b. In discussing product quality there are three terms quality assurance (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.

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

   ii. **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.

   iii. **QC** is the part of GMPs that focuses on product sampling, specification review, and product testing. QC 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.

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

d. In accordance with national legislation, procurement should be limited to only those products approved by the concerned national 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. 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.

10.10 International Commercial Terms (Incoterms) for International Procurement

a. 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.

b. 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, implying that the seller will pay in due time.

c. 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 and the purchase contracts must reference the applicable version. The information in this manual is based on Incoterms 2020. *(Link attached in references)*

10.11 Letters of Credit and Other Payment Options

a. Letters of Credit are banking instruments commonly used in international trade. They have advantages for both the Buyer and the Seller.

b. The Seller is assured he will receive prompt payment and the Buyer is assured he will be able to enforce contract conditions such as quality requirements and shipping dates.

c. The Government of Punjab, however, may not want to open an irrevocable LC to pay for purchases under international competitive bidding procedures.

10.12 Formulation of Technical Specifications

a. Detailed technical specifications are critical to successful procurement because they give potential suppliers an accurate, complete picture of what is required.

b. 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.

c. Under the bidding format used by both the Government of Punjab 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. In addition, the draft bidding documents for the procurement of goods (***ANNEX-05***) provide detailed guidance on goods specifications.

10.13 Timeline for Procurement

a. Public sector procurement by ICB does not happen quickly. More time may be needed for activities of the procurement office, evaluation committees, approval, and time periods for manufacturing and shipping. Therefore, it could be within the bid validity period as defined by procuring agency in bidding document

b. There are many variables of timeline, including, but not limited to:
   i. Procedures and approvals in force at different financial thresholds.
   ii. Supply issues, such as marketplace shortages.
   iii. Technical issues, such as availability of detailed specifications.
   iv. QA issues for pharmaceutical products in Pakistan.

10.14 Code of Ethics

The Government of Punjab also promotes a business code of ethics for the professional behavior of personnel engaged in procurement and contracting activities. This code is based the PPR 2014 Rule 2 Definition sub-rule (1) (p) Corrupt and Fraudulent Practices (see annexure for copy of the Code of Business Ethics and Integrity Pact) (***ANNEX-01).***

6 Planning & Preparation

10.1 Procurement Planning

a. Because of the long timeframe associated with competitive public-sector procurement, realistic planning is very important. It is especially critical for health care commodities because stock outs of such items can cause numerous problems.
b. Rule 8 of PPR 2014 states, "A procuring agency shall, within one month of the commencement of a financial year, devise annual planning for all proposed procurements with the object of realistically determining the requirements of the procuring agency, within its available resources, delivery time or completion date and benefits that shall be the mandate of procuring agency in the future".

10.2 Budget Process and Operational Plan

a. Beginning in each financial year, managers of Health Care Facilities are asked to review their program goals and activities for the coming fiscal year (1st July to 30th June), consider probable resources (budget) and estimate goods, equipment and services that will need to be purchased. These plans and estimates are submitted to the respective departments where changes are sometimes made. The resulting operational plans and budgets are consolidated and forwarded to the government for financial approval.
b. After the Annual Operational Plans have been refined and approved by the government, managers of HCEs are responsible for communicating their approved requirements, usually in the form of a completed Procurement Requisition, to the appropriate procuring units, along with basic specifications and cost estimates within their approved budgets.
c. Two things are used to decide the amounts needed per year for procurement of goods/services/works:
    i. An estimate based on accurate data and other factors. Trained specialists may be needed to help with this step.
    ii. An account of how much stock is in hand and how much has been ordered but not yet delivered.
d. However, sometimes goods may be purchased in quantities determined by budget availability, so re-supply calculations would not be relevant.

6.2.1 Procurement Plan

Procurement plans are developed that include tentative, package-wise schedules for purchasing activities. Procurement plans include a broad description of the goods to be purchased, a budget amount and source, a time period in which the goods will be procured and the method of procurement. The Government of Punjab uses procurement plans to organize annual revenue expenditures for goods and services.

6.2.2 Confirm Availability of Funds

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

6.2.3 Process for Developing an Annual Procurement Plan

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

6.2.3.1 Gather Information

The assigned procurement unit should receive procurement information early in the year to allow for sufficient time to process and procure the requirement. However, when procurement information is not provided in a timely manner, it may become provided by a specified deadline.

a. Send a letter to all users to submit their requirement for goods for the next fiscal year by a specified deadline.
b. Send a reminder letter to users who do not respond within time, with copies to the next higher-level office stating the need to submit requirements by the specified deadline.
c. Prepare a list of users who have failed to submit their requirements by the final deadline.
d. 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.

6.2.3.2 Begin Filling out the Procurement Plan

The procurement unit should begin filling out the Procurement Plan.

a. Describe the goods and enter the unit and quantities required.
b. Show the estimated cost of the goods and source of funds for each procurement.
c. Enter the procurement method for example, International Competitive Bidding (ICB).
d. Indicate the contract approving authority for each, procurement, per financial thresholds.

6.2.3.3 Estimate Timeframes and Complete the Procurement Plan

a. 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 goods being procured.
b. 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, Advance Acceptance of Tender, signing of contract, and completion of contract.

10.3 Preparation for Procurement

6.3.1 Analyze Procurement Requirements

The procurement unit(s) must review requirements received from HCEs i.e. procurement requisition. Analyze their needs in terms of following basis.

a. Type of goods
b. Estimated quantity and cost of goods
c. Potential sources of goods
d. Prior review requirements, etc.
e. Type of supply available i.e. after production, off-the-shelf, or from wide range of market, etc.
f. Estimated lead time for delivery
g. Previous frequency of purchase.

At times, the procurement unit may need to prepare a procurement requisition.

6.3.2 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 - 65 of PPR 2014.

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:

a. Signed procurement requisition
b. Product specifications
c. Budget estimate
d. Procurement plan and summary
e. Pre-qualification document
f. Record of advertisement
g. Bidding documents
h. Record of pre-bid conference
i. Bidders list / Attendance Sheet
j. Bid security documentation
k. Modifications to bidding documents
l. Proposals from suppliers
m. Record of bid opening
n. Record of bid examination
o. Bid review committee summary
p. Award letter
q. Performance guarantee documentation
r. Signed contract

s. Bidder notification
t. Authorization for shipment
u. Shipping documents
v. Receiving report
w. Miscellaneous correspondence

6.3.3 Procurement Record Retention

Rule-65 of PPR 2014 requires procuring entities to preserve records and documents concerning 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, in the case of development projects.

6.3.4 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;

a. Description and function of the goods in enough detail for development of a technical specification
b. Unit of measure—each, kilograms, or pounds, cycles, gross, tubes, vials, unit packs, etc.
c. Quantity
d. Confirmed budget
e. Procurement method
f. Estimated Date for completion of procurement process
g. Final destination—within Punjab, usually the Central Warehouse
h. Shipping terms—CIP, EXW, etc.
i. Payment terms—cash in advance, down payment, L/C, etc.
j. Name and address ofconsignee
k. Project identification numbers
l. Procurement approval date
m. Approvals from competent authority
n. Special requirements for contract—including QA testing
o. Special marking requirements for shipping boxes
p. Source of funds
q. Notes about special features of the goods/programs they will be used for, or the overall market situation.

6.3.5 Development of Technical Specifications

Technical experts are often needed to help translate the approved requirements into technical specifications that will give an accurate and complete picture of what is required of potential suppliers. The specifications must comply with Rule-10 of PPR 2014.

Early in the procurement process, technical consultants or end users may need to ask managers of HCEs/relevant 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.

6.3.6 Obtain Approvals

Under Rule-11 of PPR 2014 approval by the relevant authority of the procurement plan constitutes administrative and financial approval for the following

a. Procurement of the goods included in the plan
b. Method of procurement
c. Time schedule for procurement, as shown in the procurement plan
d. Prior approval requirements.

7 STANDARD BIDDING DOCUMENTS

10.1 Introduction.

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

Under Rule - 33(1) and 33(2) of PPR 2014: "No bidder shall be allowed to alter or modify his bid after the closing time for submission of bids. The procuring agency may, if necessary after opening of the bids, seek and accept such clarifications of the bid as do not change the substance of the bid."

10.2 Description of Standard Bidding Documents (SBDs)

The SBD (***ANNEX-04 & ANNEX-05***) includes guidance notes and instructions for the procuring agency and the bidder. The SBD contains all the relevant information which can be molded as per the requirement of the Procuring agency for different types of procurement.

7.2.1 Invitation for Bids (IFB)

The IFB is a copy of the advertisement or notification announcing the opportunity to bid.

7.2.2 Instructions to Bidders (ITB)

The ITB gives each relevant information to bidders for preparing and submitting their bids. It also explains the rules and procedures for the following.

a. Bid submission
b. Bid opening
c. Bid evaluation
d. Award of the contract
e. Definitions and warnings about fraud and corruption
f. Any other instruction which procuring agency seek relevant

7.2.3 Bid Data Sheet (BDS)

The BDS provides information specific to the procurement actions. It includes, but is not limited to:

a. Amount and type of bid security, if required
b. Directions for submitting bids, including markings and timeframe
c. Dates, times, and other specific information about bid opening
d. Specific criteria that will be used to evaluate bids, including any factors, other than price, that will be applied
e. Criteria for eligibility of goods, and the particular documents required to establish eligibility and conformity to bidding documents
f. Specific information about awarding the contract.

7.2.4 In-eligible Bidders

Lists of firms that are excluded from bidding on specific contracts are on the PPRA website. International agencies like the World Bank, USAID, UNICEF, UNFPA, WHO, Asian Development Bank (ADB), and others also maintain lists of firms that are ineligible from bidding on their contracts because the bidder willfully, or with gross negligence has violated the provisions of bidding document. The procurement unit may not enter into any contract with blacklisted firms.

7.2.5 General Conditions of Contract (GCC)

These widely used clauses will apply to the future contract(s). This section must be included in the bidding documents as per requirements of the respective procuring agency. GCC covers standard, normal contract issues, such as:

a. Delivery payments
b. Warranty
c. Termination
d. Force majeure
e. Governing language
f. Notices.

Changes and additions are made through Special Conditions of Contract.

7.2.6 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:

a. Requirement for immediate notification of air shipments
b. Regulatory compliance issues
c. Pre-shipment inspection and testing of different procurements if required.
d. Any unacceptable trans-shipment points
e. Any other Special condition which procuring agency deemed necessary.

7.2.7 Technical Specifications

These are precise technical descriptions of the goods to be supplied prepared by the Purchaser's technical expert. 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 evaluate the bids. The technical specifications must be in line with Rule 10 of PPR 2014 (***ANNEX-01)***. They must include a complete description of the product, presented in an industry-standard vocabulary and format, which includes, but is not limited to:

a. Technical and performance characteristics.
b. Size, units, quantity and intended use.
c. Packaging, packing, and marking.
d. Regulatory requirements.

e. Applicable standards and required certifications.
f. Quality assurance criteria, including detailed tests required.
g. Acceptance criteria.
h. Detailed activities to be performed by the supplier, if required.
i. List of detailed functional guarantees covered by the warranty.

7.2.8 List of Requirements

Lists the goods and required delivery schedules. The procuring agency fills out a form provided in the standard bidding documents that specifies:

a. Named items required for purchase
b. Quantities
c. Delivery schedule and place
d. Late delivery charges.
e. Any other which procuring agency deemed necessary.

7.2.9 Evaluation and Qualification Criteria

The procuring agency announces criteria in the SBD (Rule 31, PPR 2014) that will be used to determine the lowest evaluated bid, and the bidder's qualification requirements. Qualification criteria usually include, but are not limited to:

a. Financial capability in terms of average annual turnover during each of the past years, as shown by audited financial statements.
b. Experience and technical capacity demonstrated by the number of years manufacturing and/or selling the goods to be supplied, completed similar contracts including contact information for verification and bank references.
c. Where applicable, licensing and registration by the concerned Regulatory Authority.

10.3 Bid Submission

7.3.1 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 (***ANNEX-05)***.

7.3.2 Price Schedule

To be completed and signed by the bidder. It may includes the following:

a. Itemized charges for the unit price of goods, domestic value added (as per policy of government), freight, and insurance.
b. To calculate a margin of preference for locally manufactured products, as per the government policy, separates foreign and domestic bidders (***ANNEX-05)***.

7.3.3 Manufacturer's Authorization Letter

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

a. Authorized named party (bidder) to submit a bid.
b. Confirms warranty obligation.

(***ANNEX-05)***.

7.3.4 Bid Security Form

To be filled in and signed by guarantor (bank) or used as an example for document on guarantor's letter head. It entails the following:

a. Guarantor's undertaking to pay a specified amount (not exceeding 5 percent of the bid prices-Rule-27 of PPR 2014) if the bidder receives an award but fails to go forward with a contract the bid security may be forfeited.

7.3.5 Contract Agreement Form

To be signed by procuring agency and winning firm.

Incorporates relevant sections of bid documents into binding contract.

a. General Conditions of Contract
b. Special Conditions of Contract
c. Technical Specification and Schedule of Requirements
d. Supplier's bid and original price schedules
e. Purchaser's Advance Acceptance of Tender
f. Any other documents specified by purchaser.

7.3.6 Performance Security Form

To be filled in and signed by the guarantor (bank). Guarantor's undertaking to pay specified amount (not exceeding 10 percent of contract price. See Rule-56 of PPR 2014) if awarded bidder defaults on contract.

7.3.7 Bank Guarantee for Advance Payments

To be filled in and signed by the guarantor (bank). Guarantor's undertaking to pay a specified amount if the supplier uses advance payment for any purpose other than for delivery of the goods.

7.3.8 Certificate of Pharmaceutical Product

To be provided by manufacturer of pharmaceutical goods. It entails the following:

a. 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.
b. Part of a scheme developed by WHO to combat the sale and distribution of sub-standard and/or counterfeit pharmaceutical products.

10.4 Process for Preparing Documents for Procurement

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;

a. BDs
b. Special Conditions of Contract
c. Evaluation and qualification criteria
d. Schedule of requirements
e. Technical specifications.

7.4.1 Select and Study the SBD

Procurement staff and managers should select the SBD that best suits the requirements and the procurement method approved in the Procurement Plan and study each section of the selected document thoroughly.

7.4.2 Obtain Technical Specifications

Technical specifications include different things, depending on the type of product to be purchased.

For pharmaceutical goods procurement, the following may be considered:

a. Chemical and pharmacological attributes
b. Quality and safety issues
c. Shelf life
d. Presentation (primary packaging)
e. Pre-shipment inspection (and possibly testing)
f. Labeling.

7.4.3 Prepare Schedule of Requirements

a. Review the procurement plan and summary description of planned procurement before working on the schedule of requirements.
b. Read the guidance notes and fill out the schedule of requirements as follows:
    i. **Procurement plan**: Insert a sequential number to identify the procurement plan.
    ii. **Description**: Write a short description of the goods available in annexure just enough to clearly identify the product. The technical specifications will have a more detailed description.
    iii. **Quantity**: Enter the total quantity that will be purchased under the contract. Do not mention partial shipment amounts.
    iv. **Delivery schedule**: Establish the date when the end user needs the goods, then carefully calculate a delivery date, taking into account the implications of Incoterms, such as CIP, that will apply to the procurement contract.
    v. **Mode of shipment**: Enter air, ocean, truck, etc.
    vi. **Point of delivery**: For international procurement, usually determined by the Incoterm, as noted above.
    vii. **Special notes**: Additional information, explanations, or qualifications can be added at the bottom of the form.

7.4.4 Drafting the Bid Data Sheet

The function of the BDS is to modify and augment information and requirements printed in the Instructions to Bidders (ITB). Text in the ITB mentions the bid data sheet whenever specific information or requirements are needed to complete the instructions. Which may contains the following.

a. Read and understand clause(s) in ITB that corresponds to the required DBS information.
b. Consider whether ITB and standard data sheet clauses will adequately represent the procurement to be undertaken. Additional clauses may be included, so long as they do not contradict the standard instructions to bidders or the PPR 2014 rules.
c. List the information still needed to complete the Bid data sheet.
d. Price of bidding documents
e. Amounts of bid security

f. Amount of performance guarantee
g. If samples are required
h. Date and time for pre-bid meeting, if required
i. Bid opening date and time, bid validity requirement
j. If the evaluation will be based on items or lots
k. Bid currency and bid language.
l. Any other information required by the procuring agency.

7.4.5 Specify Eligibility Criteria and Documents Required

All interested bidders, national or international, firms and individuals, shall be allowed to bid for any project where open competitive bidding is adopted. However, competition may be restricted if, as a matter of law, in accordance with Rule 21 of PPR 2014. Eligibility requirements are primarily based on whether or not a firm has been blacklisted.

a. Determine and list any criteria on the Bid Data Sheet for eligibility, in addition to those already mentioned in the ITB.
b. For the health sector documents, use standard protocols for the Drafting bid data sheet, about procurement-specific documentation of conformity with bidding documents and registration with the DRAP(*ANNEX-03*)
c. Easy access to information.

7.4.6 Specify Evaluation Criteria and Documents Required

Determine criteria that will be used to evaluate and compare bids under Rules 31 of PPR 2014. This will relate primarily to price adjustments and the application of economic factors. Examples include:

a. Domestic preference (as per the policy of government)
b. Technical Criteria as described in SBD***(ANNEX-05)***
c. Efficiency factors
d. Delivery.
e. Insert the information for the bidder on how non- financial items will be evaluated.
f. Mention the possibility of early delivery in the Schedule of Requirements.

7.4.7 Specify Qualification Criteria and Documents Required for Evidence

It is at the discretion of the procuring agency to develop specific criteria that will be used to decide whether or not a bidder is qualified for a contract award.

SBDs for goods procurement require following basic bidder qualifications:

a. The manufacturer must have adequate production capacity and experience.
b. The manufacturer must have verifiable technical capability.
c. The bidder must have verifiable business and financial stability.
d. The bidder must have a history of successful performance
e. Determine and list documentary evidence that bidders should submit to establish (or confirm) their qualifications.
f. The firm's financial information and audited financial statements, details of current

commitments, contracts completed over the past several years.

7.4.8 Specify Addition Document Comprising the Bid

The ITB not only specifies what documents will comprise the bid, but also gives the procuring agency a chance to include more in this list through the respective BDS.

7.4.9 Begin Drafting Special Conditions of Contract (SCC)

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

a. Read and understand the clause(s) in the appropriate version of GCC corresponding to the special conditions requiring completion.
b. 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.
c. Fill in all known information; for example, the nature of goods to be supplied, purchaser's name and address, etc.
d. List the information and decisions that are still needed to complete the SCC/PCC (referenced by clause number).
e. Consider possible sources where missing information might be obtained. For example, from any authority at provincial and district level, earlier bidding document, consultant, specifications, DRAP, PPR 2014 and so on.
f. Pursue and coordinate necessary decisions. For example:
    i. Documents that will become part of the contract
    ii. Packing, marking, documentation requirements
    iii. Method and conditions of payment
    iv. Inspections and tests required
    v. List the resources and capabilities that will be needed during the execution of the contract.
    vi. 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

7.4.10 Enter Specifics for Certification of Goods/Drugs Clause

Pharmaceutical goods require registration with the Drugs Regulatory Authority, Government of Pakistan (where required), and contracts generally cannot become effective until this has been accomplished.

SCC asks for details of registration, provides wording in the case of goods have already been registered or registration is not required and provides a limit on how much time can pass before the contract will be considered null and void.

7.4.11 Enter Specifics for Inspections and Tests Clauses

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

a. Pre-shipment compliance by supplier
b. Pre-shipment compliance by purchaser
c. General dockside sampling and inspection (government import program)
d. Acceptance testing in Pakistan
e. Pre-shipment inspection and sampling is conducted at the manufacturer's facility, and 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 goods/medicines and should be known as a pre-shipment compliance program.

7.4.12 Enter Specifics for Packing, Marking and Package Documents Clauses

List the requirements that are in addition to the GCC text and provide a cross-reference to corresponding requirements in Schedule of Requirements and Technical Specifications. For example, you may want certain information printed on the outside of the packing boxes in order to facilitate warehousing and distribution, or there may be a requirement to pack goods/medicines so they remain below a certain temperature, as is the case with vaccines.

7.4.13 Enter Specifics for Shipping and Other Documents to be furnished by the Supplier

Determine and list shipping documents that will be required, including the following:

a. Commercial invoice
b. Air waybill (AWB)
c. Clean on-board Bill of Landing (B/L)
d. Packing list
e. Certificate of Analysis.

7.4.14 Construct the Invitation for Bids

Using information in the completed BDS, SCC, and Specifications and Schedule of Requirements, prepare the IFBS by following the format and directions provided in the SDB. (***ANNEX-05)***

7.4.15 Compile Draft Bidding Documents Package

The bidding documents must be compiled in accordance with Rule 24 and 25 of PPR 2014. Some of the sections/information that is part of the bidding document include:

a. IFB

b. Instructions to Bidders
c. BDS
d. GCC
e. SCC
f. Schedule of requirements
g. Technical specifications
h. Eligibility for provision of goods
i. Forms to be filled out, referenced, or used by the bidder (Bid Form, Price Sheet, Bid Security, etc.).

7.4.16 Prepare Prospective Bidders' List

The procuring agency will develop a list of suppliers that may be able to provide the required goods. 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:

a. Responders to general procurement notice
b. Prior marketing knowledge
c. Firms previously enlisted by the government
d. Firms pre-qualified by an earlier formal process.

7.4.17 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:

a. Check the draft against the procurement plan
b. Verify authenticity of the requirement of the goods
c. Investigate any other relevant factors
d. Ensure the technical specifications are accurate and include appropriate detail
e. Ensure that any evaluation criteria, in addition to price, are clearly stated and appropriate for program needs
f. Endorse (approve) the draft bidding documents for onward disposal, with or without revision.

8 INVITATION AND RECEIPT OF BIDS

10.1 Steps for Inviting Bids

8.1.1 Advertise the Opportunity to Participate in Bidding

As soon as the relevant authority approves the draft bidding document, the procuring agency 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 worth more than Rs. 200,000 and up to 3 million rupees will be advertised by timely notifications on the authority's website (www.ppra.punjab.gov.pk), and if possible, in print media using the manner and format prescribed in Rule 12(1) of PPR 2014. All procurement opportunities over 3 million PKR shall be advertised on the authority's website, as well as in the newspapers as prescribed under Rule 12(2) of PPR 2014.

For international competitive bidding, the procurement opportunity be published in print media or newspapers with a wide circulation, as well as on the website of the concerned departments, and at any international advertisement portal. Print media advertisements should be placed in at least two daily national newspapers, one each in Urdu and English. See annexure for a sample format for advertising an international competitive bid.

a. Prepare a version of the Invitation for Bids that is suitable for newspaper and periodical publication.
b. Using the format identified in ***ANNEX-05*** prepare a version of the Invitation for Bids that is suitable for website publication. Submit the advertisement following instructions and using facilities provided on the appropriate website.
c. For international competitive procurement, also place advertisements in appropriate international journals, publications, and websites.
d. Post notices at the procuring agency and on official or public notice boards.
e. Inform all the Chambers of Commerce in Pakistan.
f. In the case of ICB, send notices to foreign embassies and trade missions present in Pakistan.

8.1.2 Prepare Bidding Document Sets and a Document Register

Documents must be ready for issue or sale to interested parties at the time the advertisement appears. The bidding documents will be issued for at least 15 days for NCB and at least 30 days for ICB (Rule 25(1) of PPR 2014).

a. Determine the number of bidding document , based on:
    i. Type of goods to be purchased
    ii. Approximate number of prospective bidders, for example, a small number for goods
    iii. Source of goods; national or international
    iv. Previous sale of bidding documents for similar goods.
b. Determine the number of bidding document sets needed for official departmental purposes.
c. All procuring agencies will display the bidding documents on the website of the authority and the procuring agency, in case the procuring agency has its own website. The bidders can submit

bids on the bidding documents issues by the procuring agency or download them from the authority's website.

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

8.1.3 Prepare Systems for Safeguarding Bids, Cash and Securities

a. 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.
b. Set up a system for managing the funds collected from the prospective bidders for the cost of the bidding documents.
c. Set up a system for safeguarding securities after bids have been opened.

8.1.4 Set up Procedure for Transmitting Bidding Documents to Prospective Bidders Outside of Pakistan

a. Select methods - mail, courier, express document service.
b. Arrange capacity for paying postage or courier fees.

8.1.5 Availability of Bidding Documents to Bidders

a. The procuring agency 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. (Rule 25(7) of PPR 2014)
b. 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.
c. Provide receipts to bidders with name, address, date, and time the bidder received the bidding documents (if sold).

10.2 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.

8.2.1 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 Participants may include:

a. Representatives from every intending and prospective bidder
b. All officers and directors of procuring agency with a major role in developing or approving the draft bidding documents. These individuals can be organized into a bidding document finalization committee

8.2.2 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.

8.2.3 Hold the Pre-Bid Conference

a. Register participants and generate an attendance list, including titles and contact information.
b. Record the minutes.
c. Announce the replies to registered participants and all registered bidders via minutes of pre-bid meeting.
d. 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.

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

a. Send the minutes and other related information to all prospective bidders.

8.2.5 Extend the Bid Submission Deadline if Necessary

a. Notify prospective bidders if the bid submission deadline is extended through corrigendum.
b. The advertisement of an extension shall be made in time and manner similar to the original advertisement.

8.2.6 Receiving and Managing Bids

a. 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 procuring agency.
b. Stamp bid envelopes with the date and time they are received.
c. 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.

9 Bid Opening, Evaluation and Selection

10.1 Introduction

The procedure described in this manual is based on single-stage-two-envelope bidding process which is commonly adopted for procurement of goods (under Rule-38 (2)(a)) of PPR 2014) when the bids are evaluated on technical and financial grounds. The rule states:

a. The bid shall be a single package consisting of two separate envelopes, containing separately the financial and the technical proposals.
b. The envelopes shall be marked as Financial Proposal and Technical Proposal.
c. In the first instance, the Technical Proposal shall be opened and the envelope marked as Financial Proposal shall be retained unopened in the custody of the procuring agency.
d. The procuring agency shall evaluate the technical proposal in the manner prescribed in advance, without reference to the price and shall reject any proposal which does not conform to the specified requirements.
e. During the technical evaluation, no amendments in the technical proposal shall be permitted.
f. After the evaluation and approval of the technical proposals, the procuring agency shall open the financial proposals of the technically accepted bids, publicly at a time, date and venue announced and communicated to the bidders in advance, within the bid validity period.
g. The financial bids found technically nonresponsive shall be returned un-opened to the respective bidders.
h. The lowest evaluated bidder shall be awarded the contract.
i. The evaluation and selection of a winning bidder is governed by the Rule-32 of PPR 2014 (***ANNEX-01)***

10.2 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-30 of PPR 2014.

9.2.1 Organize the Bid Opening (Officers of Procuring Agency)

a. Notify members of procurement committee before the bid opening.
b. Arrange the place for bid opening, as specified in the bidding documents.
c. Hold all bids unopened and secure until the date and hour designated in the bidding documents.

9.2.2 Record Bid Submissions

As the bids arrive, the officers of the procuring agency should do the following:

a. Provide receipts
b. Record the bidder name and the submission date. (Bids received after the exact deadline will not be opened)

9.2.3 Hold Bid Opening (Bid Opening Committee)

On the date and at the time and place specified on the bidding documents:

a. Participants

i. Authorized bidders
ii. Others directly involved with the subject procurement, for example, consultants hired for the purpose.

b. Rule 30(3) of PPR 2014, requires each attendee to register on an attendance sheet provided for that purpose, and include—:
   i. Name and address
   ii. Company, manufacturer, representative
   iii. Organizational affiliation (if not bidder)
   iv. Signature.

   Ensure that a member of the procurement committee countersigns the attendance sheet.

c. Open all bids received before the deadline, one at a time, and read the bid aloud with special focus on the following:
   i. Bidder's name and local agent's name, if different
   ii. Bidder's city/state or province/country
   iii. Quoted items.

d. Hold all financial bid envelopes unopened in a box, to be opened at a later date, after the technical evaluation.
   i. Record all samples received.
   ii. Do not open bids received after the deadline, bids may be returned unopened (Rule 30(4) of PPR 2014).

9.2.4 Record and Distribute Details (Bid Opening Committee)

a. As each bid is read, complete a bid opening checklist as described in SBD. At this stage, if the bid was received on time, it cannot be eliminated, even if something appears to be missing or incorrect.
b. Record the details of the bid on a Bid Opening Sheet (BOS)/ attendance sheet.
c. Require all members of the procurement committee, and the bidders, or their representatives who attend the bid opening, to sign the BOS/ attendance sheet before or after the opening is complete.
d. If only one bid is received, the following considerations may be entertained:
   i. Punjab Procurement Rules 2014 don't put any limit on number of tenders / bids received in response to tender notices provided that the procurement opportunity has been advertised in the prescribed manner. The single bid may be considered if it meets the evaluation criteria expressed in tender notice and is not in conflict with any other rules, regulations or policy of the Punjab Government. However, the procuring agency should make a decision with due diligence and in the light of Rule 4 PPR 2014.
   ii. Whenever a procuring agency is confronted with such a situation whereby the rate quoted by the single bidder cannot be compared so as to declare it as the lowest rate or otherwise it may make a prudent decision. While making a decision, the following factors may be kept in view:
      - The comparison of price of the goods if procured during the current financial

year.

- Market price of the goods to be procured.

iii. In case abnormal increase in prices is observed, the procuring agency may like to re-advertise the procurement opportunity, if time permits.

10.3 Bid Evaluation Format

PPR's 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 31 of PPR 2014. Step-by-step guidance for members of evaluation committee are given below:

9.3.1 Standard Bid Evaluation Form (SBEF) Documents

The SBEF (***ANNEX-04***) provides tables and forms designed to help procuring entities examine and evaluate each bid submission and arrive at a winning bid based on a fair application of the rules, procedures and requirements set down in the bidding documents. This chapter will use the SBEF to explain the bid opening, evaluation and award stages for procurement of goods based on Rule 38 (2)(b) of PPR 2014 Single stage – two envelope, procedure.

10.4 Steps for Organizing the Evaluation Process

9.4.1 Fill out SBEF Tables 1-3

a. Fill out SBEF Table 1, Identification; It requires basic information about the subject procurement package, most of which can be found in the approved Procurement Plan, including the original cost estimate. The remaining information is located in the Bidding document.
b. Fill out SBEF Table 2, Bidding Process; with basic information about the bidding process, which includes publication dates, title of bidding documents, and amendment dates.
c. Fill out SBEF Table 3, Bid Submission and Opening; with information about the bid submission and opening which includes deadline and opening dates, bid validity period and number of bids received.

9.4.2 Check Copies and Secure Bid Originals

a. Compare each copy of each bid with its original and correct accordingly, if necessary.
b. Confirm that signatures on each original are present as required.
c. Keep originals in a safe location and use copies for evaluation work.

9.4.3 Complete the Bid Opening Checklist for Each Bid

a. Enter any incomplete information. For example, descriptions at bid opening may need to be elaborated further.
b. Verify information recorded at bid opening.
c. Hold the financial bid envelops unopened in a box which should be opened after the technical evaluation process at a later date

10.5 Steps for Technical Evaluation of Bids

The examination outlined in SBEF table 4 ***(ANNEX-04)*** 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.

9.5.1 Review Original Bidding Documents

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

a. Thoroughly review the original bidding document issued for the procurement.
b. 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

9.5.2 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.

9.5.3 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.

a. Examine each bid for modifications, exceptions, and interlineations (notations written between the lines of the original bidding documents) regarding;
    i. Compliance with technical specifications provided in the bidding documents.
    ii. 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.
b. List and cross-reference deviations from the bidding documents and indicate whether or not they are acceptable or unacceptable; include the reasons.
c. For each bid record, document the findings for compliance with technical specifications. 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 and it must be mentioned in the bidding documents.

d. If bidders are required to submit samples for inspection and/or testing, it is the procuring agency'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.
e. Summarize findings and provide overall comments on the technical evaluation.

9.5.4 Undertake Verification Exercise (Table 4 - Column B)

A sample checklist for Column B of Table 4 ***(ANNEX-04)*** 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 Procurement committee should:

a. Review bidding documents for items to be checked in this category and prepare a checklist.
b. 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 must be considered.
c. Do not consider any information contained in a bid submission that was not specifically requested in the bidding document.

9.5.5 Assess Eligibility of Bidder (Table 4 - Column C)

The Bid Evaluation Committee (BEC) should:

a. Check the PPRA website or any other reliable website for a list of debarred firms.
b. Confirm the eligibility of each bidder and the goods offered.
c. If pre-qualification has taken place, only bids from pre-qualified bidders can be considered.

9.5.6 Examine Bids for Completeness: Table 4 - column d

SBEF Table 4 may be used for recording details about the completeness of the bid.

a. Review bidding documents for items to be checked in this category and prepare a list.
b. Review the bids and note if any are incomplete or deviate from the original documents.
    i. Unless the bidding documents have specifically allowed bidders to quote for only select items or for only partial quantities of an item, bids not offering all of the required items (both type and quantity) will ordinarily be considered non-responsive. This decision requires significant judgment.
    ii. Changes or additions to the bidding document by the bidder are usually treated as deviations.

9.5.7 Examine Bids for Commercial Responsiveness (Sub-schedule for Table 4 Column E)

A sample sub-schedule for Column E of SBEF table 5 is used to examine the details of commercial responsiveness. Bidding documents may include additional issues that should be addressed during the commercial responsiveness examination.

9.5.8 Obtain and Review Technical Evaluation Report

The technical expert, or committee, indicates whether or not the bid is technically acceptable. The bid committee notes this determination in its evaluation report.

9.5.9 Identify Substantially Responsive Bids (Table 4 - Column E)

Review the technical evaluation report and the findings from the other sub-schedule evaluations of SBEF Table 4 and determine whether or not each bid is substantially responsive to the requirements terms and conditions stated in the Bidding documents. However, bids that offer deviations may be considered substantially responsive.

9.5.10 Accept Bids for Financial Examination (Table 4 - Column F)

a. List each bid and indicate whether it will be accepted for financial evaluation, based on the results of their technical evaluation and obtain approval from the relevant authority.
b. 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.
c. 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.

10.6 Steps for Financial Evaluation (SBEF Table 5-11)

For each bid that survives the technical evaluation stage, the B must arrive at an "evaluated cost". SBEF Tables 5-11 help insure 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.

9.6.1 Complete SBEF Table 5 - Bid Prices as Read out (*ANNEX-04)*

9.6.2 Calculate Corrections and Unconditional Discounts (SBEF Table 6)

The procurement committee should use Table 6 (***ANNEX-04)*** to incorporate corrections and unconditional discounts in the calculation for an evaluated cost.

a. **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. In other words, the stated unit price prevails. If there is a discrepancy between words and figures, the amount in words prevails. Corrections are considered binding on the bidder. The procuring agency can call the bidders for verification of corrections. Explain in footnotes unusual or substantial corrections that could affect the comparative ranking of bids.
b. **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.
c. 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.

d. 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.

9.6.3 Fill out Exchange Rate (SBEF Table 7)

9.6.3.1 Check the original bidding documents (ITB). For comparison, enter the currency specified.

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

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

9.6.4 Calculate Currency Conversion—Multiple Currencies (SBEF Table 8)

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

9.6.5 Calculate Additions, Adjustments, and Priced Deviations (SBEF Table 10)

a. 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.

b. 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 is expressed in the evaluation currency and are shown in Column D.

c. 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.

d. 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.

9.6.6 Calculate Domestic Preference for Goods (SBEF Table 11)

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.

9.6.7 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).

a. 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).

b. 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.

c. 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.

d. 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 D: Total price: Enter the amounts calculated in table 10, Column F.

Column E: 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 F: revised total: Enter the amount of Column C, minus Column D.

Column G: 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.

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

10.7 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 for a sample ranking worksheet for financial evaluation.

9.7.1 Apply Any Cross Discounts

These conditional discounts are offered 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 lowest overall cost of the total contract package. Bid evaluation in these cases can be complicated with many 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 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 the columns D and E and include remarks.

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

10.8 Steps for Verifying Bid Securities

Bid securities in a fixed amount not exceeding 5% of the bid price under Rule 27 of PPR 2014 (specified in BDS) are submitted with financial bids from both local and international bidders. The bidding documents will state which form(s) of bid security can be accepted.

Generally accepted securities include:

a. Pay order
b. Bank draft
c. Bank guarantee

No cash money is allowed.

Make sure that all bid securities conform to the requirements stated in Instructions to Bidders (ITB). And bid securities must be verified before awarding the contract.

9.8.1 Safeguard and Record Bid Securities

a. Segregate bid securities soon after the financial bids are opened.
b. Hold bid securities in a locked, secure location until a contract has been awarded.
c. Record each bid security in the register set up for this purpose.
d. Verify the bid securities from the respective managements.

9.8.2 Confirm the Validity of All Bid Securities within 15 days after the Financial Bid Opening.

a. Use any legal source to confirm the bid securities issued by banks within Pakistan (local issuing banks), preferably by email/letter.
b. Confirm the bid securities issued by such banks located outside Pakistan that have a correspondent bank within Pakistan. Any legal source can be used for verification in such cases.

10.9 Steps for Qualifying Lowest Evaluated Bidder

If prequalification was conducted, the bidder whose bid is the lowest evaluated should receive the award.

The purchaser must satisfy itself fully on the following accounts.

a. 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.
b. If the lowest evaluated bidder is still qualified, include this information in the evaluation report.
c. If prequalification was not done, the lowest evaluated bidder must be post-qualified using the requirements stated in the bidding documents.

9.9.1 Develop a Bidder's Qualification Worksheet

To facilitate the qualification process, develop a bidder's qualification worksheet based on qualification criteria announced in the bidding documents (the bidder qualification criteria that can be used as a worksheet).

9.9.2 Examine Documents and Statements

a. Examine the documents and statements provided by the bidder with regard to qualification criteria announced in the bidding documents.
b. Record the findings on the worksheet.

9.9.3 Check References

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

9.9.4 Determine Qualification Status

a. Determine if the lowest evaluated bidder satisfies all the qualification criteria.
b. If the lowest evaluated bidder fails post-qualification, reject its bid, subject the next ranked bidder to the same post-qualification examination.
c. 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 within the procuring agency/any other procuring agency (in writing) may be considered adequate justification.

10.10 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;

a. Product specifications
b. Delivery requirements

c. Performance obligations of both parties
d. 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 goods 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:

a. Form of contract
b. Bid form and the price schedule submitted by the bidder
c. Schedule of requirements (offered by the bidder and accepted by the purchaser)
d. The technical specifications (offered by the bidder and accepted by the purchaser)
e. GCC
f. SCC (filled in)
g. 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:

a. Product requirements
b. Delivery requirements
c. Certification requirements
d. Inspection and testing rights
e. Payment terms
f. Special QA conditions appropriate to the commodity
g. Funder requirements (if required)
i. Warranty clauses
b. Termination clauses
c. Remedy clauses.

10.11 Recommending for Award

9.11.1 Prepare a Bid Evaluation Report

a. The procurement committee prepares a bid evaluation report that provides information documenting the bid opening process, the preliminary bid examination, the technical evaluation and the financial evaluation. 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.

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

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

d. Sign the evaluation report. Each member must sign and clearly state their name and designation.

e. If any member of the Bid evaluation committee disagrees with the recommendation, a member can write a note of dissent describing their reasons in detail.

9.11.2 Submit Report to the Approving Authority

Submit the evaluation report with recommendations for award and note of dissent, if any, to the approving authority.

10.12 Government Approvals and Authorization

a. The appropriate approving authority must formally approve the award recommendation. (Rules 11 and 63 of PPR 2014)

b. 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 Bid evaluation Committee Summary, the approving authority is responsible for promptly approving the award recommendation. By promptly approving award recommendations based on a fair and equitable bid evaluation process, the approving authority helps

a. Increase the confidence of bidders in the procurement process which encourages bidders to compete for Government of Punjab contracts, thereby increasing competition which can lead to reduced product prices.

b. Reduce the number of grievances filed by bidders if they think the approving authority made an arbitrary decision that was not based on the bid evaluation process; as required by Rule 4 of PPR 2014.

c. Support the product delivery schedule, ensure that the contract is awarded to the manufacturer in a reasonable time.

d. 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 PPR 2014.

e. The decision of the approving authority will be communicated to the procuring agency through the same route in which the request for approval was initially submitted.

f. After the procuring agency receives the approval, under Rule-55 of PPR 2014 the Advance Acceptance of Tender (AAT) for the procurement contract must be issued within the original or extended bid validity period, if no complaint or appeal is pending against the bidder.

g. For all contract awards greater that PKR 50 million, the Purchaser must complete Contract Award Performa I (see Annexure) and Contract Award Performa II (see Annexure) for posting on the PPRA website.

10.13 Announcement of Evaluation Reports

Under Rule 37 of PPR 2014, at least seven days prior to awarding the procurement

contract, the procuring agency must announce the results of the bid evaluation in a report that justifies acceptance or rejection of bids.

10.14 Extending Bid Validity (if necessary)

If justified by exceptional circumstances Rule-29 of PPR 2014, a procuring agency may request a bidder to extend the validity period of its bid. Bidders are not obliged to agree to such requests. However, if a bidder agrees, it must be in writing and confirm the new date for the expiry of bids that has been requested by the procuring entity. If the bidder has submitted bid security, the bid security must be extended as well.

10.15 Redressal of Grievances

If any bidder thinks they did not receive fair and impartial treatment after submitting their bid, they may file a written complaint in accordance with Rule 67 of PPR 2014, no later than 10 days after the announcement of the bid evaluation report.

The Grievance Committee, comprising of odd number of person, shall review the grievance and make a decision within 15 days of receipt of the complaint. Lodging a complaint by a bidder does not automatically warrant suspension of the bidding process.

10 Award, Contract & Delivery

10.1 Publication of Award

In accordance with Rule 66 of PPR 2014, as soon as a contract has been awarded, the procuring agency shall make all documents related to the evaluation of the bid and award of contract public.

10.1.1 Submit Award Information to PPRA for Publication

For contracts above PKR 50 million, complete PPRA Contract Award Performa I (see Annexure) and Contract Award Performa II (see Annexure) and submit completed Performa and any other required information to PPRA for posting on their website.

10.2 Notification of Acceptance

Prior to the expiry of the bid validity period and 10 days after publishing the Contract Award Performa on the PPRA website (if available) or department's own website, the procuring agency should issue a Notification of Acceptance (AAT) to the successful bidder (Rule-55 of PPR 2014). The AAT establishes a contract between the procuring entity and the successful bidder, which is confirmed later by signature of the contract document.

10.2.1 Prepare Notification Documents

The AAT must state the;

a. Acceptance of the bid by the procuring agency
b. Price at which the contract is awarded
c. Amount of the performance security and its format
d. Date and time within which the performance security must be submitted
e. Date and time within which the contract will be signed (see annexure for a sample AAT).

10.2.2 Resolve Minor Deviations

If the recommended bid contains minor deviations that need to be resolved, do the following:

a. Draft a letter that
b. States the offer is being conditionally accepted, pending resolution of outstanding issues
c. Lists outstanding issues and indicate the next step
d. Requests a response / acknowledgement.
e. Get concurrence, as needed, before sending the letter.
f. If deviations are resolved, proceed to award; otherwise, select the next lowest evaluated bid approved by the relevant approving authority.

10.2.3 Send the Advance Acceptance of Tender

The AAT cannot be sent until seven days after the Bid Evaluation Report has been published (Rule 37 of PPR, 2014) and the award decision and the relevant authority has approved it.

a. Transmit the AAT to the successful bidder by registered post, courier, or hand delivery. An additional advance notice can be transmitted by email or fax.
b. Send copies of the AAT 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.

10.3 Performance Security, Contract Signing and Distribution

10.3.1 Winning Bidder Submission of Performance Security and Contract Form

a. The successful bidder must submit performance security (which should not exceed 10%

of contract value) and the signed contract form to the procuring agency within the deadline mentioned in the original bidding documents (Rule 56 of PPR 2014). The contract form binds him to the general and special conditions of the contract and the specifications contained in the original bidding documents.

b. Usually, the successful bidder goes to the procurement office with his agent, turns over the performance security, and signs the contract form as the first party. Alternately, the successful bidder can send the required performance security and signatures by courier.
c. 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.
d. 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.

10.3.2 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.

a. Use any legal source to confirm the performance securities issued by banks within Pakistan (local issuing banks), preferably by speaking with a bank officer through official letter or Email.
b. Confirm performance securities issued by banks or other institutions outside Pakistan by email, fax, telegram, telex, letter, etc.
c. 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.

10.3.3 Sign the Contract on Behalf of Procuring Agency

After the successful bidder signs the contract form and provides performance security, make arrangements for the relevant authority to sign on behalf of Procuring Agency.

10.3.4 Distribute and Preserve Contract Originals

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

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

10.3.5 Distribute Contract Copies

Send a copy of the entire signed contact (form plus conditions and specifications, etc.) to the relevant authority and subordinate offices for record keeping.

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

a. Finance officer
b. Consignee
c. Central warehouse
d. Port clearance
e. Clearing and forwarding agent
f. Collector of customs duties and collector of sales tax at the port of entry
g. Supplier's local agent
h. Project finance cell

10.3.6 Notify Successful Bidder and Unsuccessful Bidders

Notify the successful bidder and the unsuccessful bidders under Rule 35 of PPR 2014 and return bid securities to the unsuccessful bidders but not before signing of the contract with first lowest bidder.

10.4 Payment Arrangements

For local procurements follow the payment procedure given in the bidding documents and under Rule-63 of PPR 2014.

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.

10.4.1 Arrange Advance Payment

If an advance payment is required, an official of the procuring agency must request funds from the appropriate financial unit on timely basis. Direct bank transfer of funds is the best choice for this transaction. It should include:

a. Seller's name, address, bank, account number, address of bank, etc.
b. Reference to procurement contract number.

10.4.2 Arrange for Opening an L/C

If the contract requires an L/C, the procurement unit should:

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

Assemble the following information and documents:

a. Program name
b. Contract number
c. Name and address of the beneficiary (seller)
d. Name and address of the beneficiary's bank, or the L/C advising bank, as applicable
e. Contract amount and the currency
f. Short description of the contracted goods
g. Any other information pertinent to the L/C application form
h. One copy of the contract
i. One copy of the schedule of requirements

Develop an L/C instruction sheet from the relevant sections of the contract, giving precise instructions about the documents against which payment can be made, shipping schedules, contract amounts, payment schedules, etc. See annexure 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.

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

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

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

10.4.3 Verify Advance Payment and/or L/C

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

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 from which date the shipping date is to be calculated.

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.

10.4.4 Facilitate L/C Amendment If Needed

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

Mistakes/errors 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.

10.5 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.

10.5.1 Set up and maintain a Contract Monitoring System

a. List the responsibilities of the purchaser and of the supplier for contract performance. See annexure for a sample list of supplier performance responsibilities.
   i. Responsibilities tied to the normal execution of the contract, such as arrangements for inspection, provision of shipping documents, etc.
   ii. Responsibilities tied to exceptional conditions, such as notification of force majeure.
b. Determine a probable shipping date, based on the date of down payment or issuance of L/C and communication with the supplier.
c. 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 for an example.
d. Evaluate the status of unfinished orders at least once every two weeks.
   iii. Update the schedule with the actual dates after tasks and responsibilities are complete.
   iv. Remind the supplier of upcoming deadlines. Ask how the work is progressing.

10.5.2 Send Shipping and Marking Instructions

a. Produce a separate set of shipping and marking instructions based on the contract document and 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 to avoid delays and customs clearance problems.
b. See Annexure for an example of shipping and marking instructions.

10.6 Pre-Shipment Inspection and Testing

10.6.1 Compliance Program for Goods and Pharmaceuticals

Contracts for Goods 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 for a sample inspection order.)

a. The Pre-shipment Compliance Program, including information on sample size.
b. The procurement unit, assisted by a technical expert, should arrange for any pre-shipment inspection, sampling, and testing well in advance of the expected shipping date.
c. Technical expert has 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.
d. Contract with qualified inspection, sampling, and testing services that the procuring agency short-listed.
e. 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.
f. 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.
g. 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.
    i. If the specifications and test reports are the same, this step is a formality.
    ii. If there are differences, the assigned technical expert must send its recommendation/report to the procuring agency.
    iii. The procurement office makes a decision and communicates it to the supplier.
h. Ensure that all corrections are made.
    i. 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.
    ii. Pharmaceutical goods will be treated as per DRAP rule.

10.7 Shipping Clearance and Notifications

10.7.1 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.

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 for a sample authorization for shipment.

10.7.2 Provide Pre-advice to Port Clearance Staff

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

10.7.3 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:

a. 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 AWB)
b. Copies of QA documents and certifications
c. Copies of commercial documents, including a performa invoice and packing list
d. Certifications for packing and marking.

10.7.4 Notify the ETA

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

a. Allows time to plan warehouse space and inland transportation
b. Alerts warehouse and logistics staff to upcoming arrival of documents. Notify program management of the ETA.

10.8 Shipping Documents

10.8.1 Seller's Distribution of Shipping Documents

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 AWB because the original is sent with the goods.

The seller puts the original B/L, or copy of the AWB, 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.

10.8.2 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 AWB copy and other shipping documents (usually, commercial invoice, packing list, and insurance papers) from the L/C opening bank.

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

a. Customs and Forwarding agent: two sets, one is the negotiable copy
b. Insurance surveyor: one set for marine insurance survey
c. Stores: one set for store receipt and store accounting
d. Procurement file: multiple sets.

10.8.3 Documents for Customs Clearance - Ocean Shipment

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

a. 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.
b. 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.

10.8.4 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.

a. The original AWB accompanies the goods. It does not confer ownership like an ocean Bill of Lading, so only proper identification is required in order to be given possession of the shipment.
b. In some cases, an Exemption Certificate of Customs Duties and VAT (CDVAT) may also be required in order to get a delivery shipment released.

10.9 Customs Clearance and Delivery

10.9.1 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:

a. Payment of port charges
b. Clearance from the port and customs
c. Joint insurance survey, both on board and at the warehouse
d. Insurance claims (if the consignment is insured and found damaged)
e. Loading, offloading and transportation from port to warehouse

10.9.2 Pre-Release Inspection

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

10.9.3 Delivery to Receiving Warehouse

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

a. Refrigeration of perishable products (for example, vaccine and insulin)
b. Protection from damage due to bad weather conditions

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

10.9.4 Warehouse Delivery Inspection

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

a. Correct commodity
b. Shipping damage
c. Special packing as required by the contract
d. Full quantities delivered
e. Packing slip present and correct
f. Correct markings on packaging, including expiry dates
g. Any further testing required
h. Manufacturer's certifications included with shipment (or documents)

10.9.5 Warehouse Reports

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

10.10 Receipt of Consignment

10.10.1 Receiving Consignments of Imports

The stores department of the procuring entity will receive the shipment from the C and F agent, along with copies of the following shipping documents:

a. Commercial invoice
b. Packing list
c. Bill of lading or AWB
d. Certificate of origin
e. Certificate of analysis
f. On board insurance survey report (if required)

10.10.2 Receiving Consignments of Domestic Goods

In case of domestic delivery on Carriage Paid-To (CPT) basis, the documents will be copies of:

a. Commercial invoice
b. Packing list
c. Truck receipt
d. Certificate of analysis

10.11 Claims and Damages

10.11.1 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;

a. Boat note
b. B/L
c. Commercial invoice
d. Packing list
e. Survey report
f. Insurance policy—to be received from the supplier in CIF contracts, to be received from the purchaser in Cost and Freight (CFR) contracts
g. Claim bill.

10.11.2 Liquidated Damages (L/D)

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

a. Determine if the supplier has accrued any L/D. This determination process requires a review of the:
   i. Contract terms and conditions for L/D
   ii. B/L showing the shipment date (the date the goods were placed onboard)
   iii. L/C advice from commercial bank showing the date it was issued
   iv. Percentage of consignment shipped within the deadlines required by the contract.
b. If the review reveals late shipment(s) subject to L/D, determine the amount.

10.11.3 Adjustment and Release of Retention Money

a. 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.

b. If the amount of the L/D is less than the amount of the retention money then releases the remaining amount to the supplier, after deducting the L/D amount. In this case, the procurement office must;
   i. State in writing exactly how L/D applies.
   ii. Determine the amount of L/D, if applicable.
   iii. Advise the supplier of the applicability and amount of L/D.
   iv. Mark invoices for amount to be paid after deducting the L/D amount, if applicable.
   v. Send invoice(s) and supporting statements and calculations to the appropriate finance office for action.

10.11.4 Warranty Claims

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

10.12 Closing the Contract

10.12.1 Contract Records

At the end of the warranty period, record if:

a. Any warranty claim(s) have been made and if they have been settled
b. Any insurance claim was applicable, lodged, and processed
c. Any L/D were applicable and, if so, the amount of L/D deducted

10.12.2 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.

10.12.3 Contract Files

Mark the file of the contract "closed" and retain it in the closed file records for a minimum of five year.

11 ANNEXURES

10.1 ANNEXURE-01 - PPRA 2009

http://ppra.punjab.gov.pk

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GOVERNMENT OF THE PUNJAB

SERVICES AND GENERAL ADMINISTRATION

DEPARTMENT

Dated Lahore, the 13th January, 2014

NOTIFICATION

No. ADMN(PPRA)10-2/2013. In exercise of the powers conferred under section 26 of the Punjab Procurement Regulatory Authority Act 2009 *(VIII of 2009)*, Governor of the Punjab is pleased to make the following rules:

1. **Short title and commencement**.– (1) These rules may be cited as the Punjab Procurement Rules 2014.

(2) They shall come into force at once.

CHAPTER-I

GENERAL PROVISIONS

2. **Definitions**.–(1) In these rules:

(a) „Act" means the Punjab Procurement Regulatory Authority Act 2009 *(VIII of 2009);*

(b) `advertisement" means an advertisement published in the manner prescribed under rule 12;

(c) `applicant" means a person or firm who seek to be enlisted or to be prequalified or to be shortlisted in response to the advertisement given by the procuring agency;

(d) „associate" means any agency or person with whom the consultant associates in order to provide any part of the services;

(e) „Authority" means the Punjab Procurement Regulatory Authority;

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(f) „bid“ means a tender or an offer, in response to an invitation, by a person, consultant, firm, company or an organization expressing his or its willingness to undertake a specified task at a price;

(g) „biding document“ means a document or a set of

documents prescribing the quantity, quality, characteristics, conditions and procedures of the transactions prior to the actual procurement and on the basis of which bidders prepare their bids;

(h) „bid security“ means the bank guarantee or other form of security submitted by a bidder together with a bid to secure the obligations of the bidder participating in a bidding proceedings;

(i) „competitive bidding“ means a procedure leading to the award of a contract whereby all the interested persons, firms, companies or organizations may bid for the contract;

(j) „competent authority“ means the head of the procuring agency or any other officer authorized to act as competent authority;

(k) „completion date“ means the date of completion of the procurement certified by the procuring agency;

(l) „consultant“ means a person or firm who or which is qualified by appropriate education and relevant experience for provision of consultancy services;

(m) „consultancy services“ means services requiring adequate technical expertise and financial capability in undertaking specific assignment or project and may be of an intellectual nature and differ from the other types of services directly connected with the procurement of goods and works in which the physical component of the activity

is the main function and often involves equipment intensive assignments and may include:

(i) advisory and review services;
(ii) pre-investment or feasibility studies;
(iii) construction supervision;
(iv) management and related services, and
(v) other technical services or special studies;
(vi) design; and
(vii) surveys and investigations;

(n) „contract" means the agreement proposed to be entered into between the procuring agency and the successful bidder;

(o) „contractor" means a person, firm, company or an organization who or which undertakes to supply goods, services or works and includes a consultant;

[1][**(p)** **********]

(q) „emergency" means natural calamity, disaster, accident, war and operational emergency which may give rise to abnormal situation requiring prompt and immediate action to limit or avoid damage to person, property or the environment;

(r) „evaluation committee" means a committee constituted by the procuring agency to evaluate tender or proposal to ascertain whether the bid"s proposal or tender correspond to the evaluation criteria formulated by the procuring agency;

(s) „evaluation report" means the report prepared after the evaluation of tenders, quotations, expression of interest, or proposal;

[1] clause (p) omitted vide Notification No.S.O(Cabinet-I)2-9/2015 dated 06.01.2016

[2] [**(sa)**„framework contract" means a contract whereby the procurement is made for a certain volume or quantity of a particular good, a set of goods, services or works over a specific period against an agreed sum or rate per item or lump sum.]

(t) „Government" means Government of the Punjab;

[3][(u) „large consultancy" means a consultancy where the cost of consultancy exceeds **two** million rupees for individual consultant and five million rupees for consulting firms and the duration of large consultancy for an individual consultant shall not exceed twelve months];

(v)lowest evaluated bid means:

(i) a bid most closely conforming to evaluation criteria and other conditions specified in the bidding document; and

(ii)having lowest evaluated cost;

(w) „performance guarantee" means the bank guarantee or other form of security submitted by the contractor to secure obligations under the contract in accordance with the requirement in the bidding document;

(x)„pre-qualification" means a procedure for demonstrating qualification as a pre-condition for being invited to tender;

(y)„proposal" means the technical proposal or the financial proposal submitted by a bidder;

(z)„repeat orders" means procurement of the same commodity from the same source;

(aa) „responsive" means qualified for consideration on the basis of declared evaluation criteria and specified in the bid document or in the request for proposal;

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[2] Inserted vide Notification No.ADMN(PPRA)10-2/2014 dated 11.03.2014

[3] in clause (u) the word "one" substituted with the word "two" vide Notification No.S.O(Cabinet-I)2-9/2015 dated 06.01.2016

[4][(ab) „short consultancy“ means consultancy where the cost of consultancy does not **exceed two** million rupees for individual consultant and five million rupees for consulting firms and duration of the short consultancies for an individual consultants shall not exceed six months];

(ac) „supplier“ means a person, firm, company or an organization who or which undertakes to supply goods, services or works;

(ad) „urgency“ means a limited timeline for the accomplishment of procurement which cannot be met through open and limited bidding method; and

(ae) „value for money“ means the best returns for each rupee spent in terms of quality, timeliness, reliability, after sales service, up-grade ability, price, source, and the combination of whole-life cost and quality to meet the procuring agency“s requirements.

(2) The expression used but not defined in these rules shall have the same meanings as is assigned to it in the Act.

[5][**3. Scope and applicability**.– Save as otherwise provided, these rules shall apply to all **public** procurements made by all procuring agencies whether within or outside the Punjab].

4. Principles of procurements.– A procuring agency, while making any procurement, shall ensure that the procurement is made in a fair and transparent manner, the object of procurement brings value for money to the procuring agency and the procurement process is efficient and economical.

5. International commitments of the Government.– If any provision of these rules is in conflict with any obligation or

commitment of the Government arising out of an international

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[4] in clause (ab) The words “exceeds one” substituted with the words “exceed two” vide Notification

No.S.O(Cabinet-I)2-9/2015 dated 06.01.2016

[5] The word “public” inserted before the word “procurements” vide Notification No.S.O(Cabinet-I)2-9/2015 dated 06.01.2016.

agreement with a state or states, or any international financial institution, the provisions of such international agreement, to the extent of conflict, shall prevail.

6. Language.–(1) Subject to sub-rule (2), all communication and documentation relating to procurements of the Government shall either be in Urdu or English or both.

(2) When any procurement is required to be made from any state outside Pakistan, the language of that state may also be used in addition to Urdu or English but the original documentation for purposes of record, even in that case, shall be in Urdu or English and the translation in such other language may be used for any other purpose.

(3) In case of conflict, the original documentation on record shall prevail.

7. Integrity pact.– Procurement exceeding the limit specified in the regulations shall be subject to an integrity pact between the procuring agency and a contractor.

CHAPTER-II

PROCUREMENT PLANNING

8. Procurement planning.– A procuring agency shall, within one month from the commencement of a financial year, devise annual planning for all proposed procurements with the object of realistically determining the requirements of the procuring agency, within its available resources, delivery time or completion date and benefits that are likely to accrue to the procuring agency in future.

9. Limitation on splitting of procurement.– Save as otherwise provided and subject to the regulations, a procuring agency shall announce in an appropriate manner all proposed procurements for each financial year and shall proceed accordingly without any splitting or regrouping of the procurements so planned.

(2) The procuring agency shall advertise in advance annual requirements for procurement on the website of the Authority as well as on its website.

10. Specifications.–(1) A procuring agency shall determine specifications in a manner to allow the widest possible competition which shall not favour any single contractor nor put others at a disadvantage.

(2) The specifications shall be generic and shall not include references to brand names, model numbers, catalogue numbers or similar other classifications but if the procuring agency is satisfied that the use of, or 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".

(3) The provisions contained in sub-rules (1) and (2) shall not apply to any procurement made by a procuring agency which is a public sector commercial concern on the demand of a private sector client specifying, in writing, a particular brand, model or classification of equipment, machinery or other objects.

11. Approval mechanism.– All procuring agencies shall provide clear authorization and delegation of powers for different categories of procurement and shall initiate procurements after prior approval of the competent authority.

CHAPTER-III

ADVERTISEMENT

[6][**12. Method of advertisement**.– (1) **Save as otherwise provided in these rules**, a procuring agency shall advertise procurement of more than [7][**two**] hundred thousand rupees and up to

[6]The expression "Subject to rule 59" substituted with the expression "Save as otherwise provided in these rules" vide Notification No.S.O(Cabinet-I)2-9/2015 dated 06.01.2016.

[7] The expression "one" substituted with the expression "two" vide Notification No. SO(Cab-I)2-9/2015 dated 17.08.2020

the limit of [8][**three**] million rupees on the website of the Authority in the manner and format specified by regulations but if deemed in public interest, the procuring agency may also advertise the procurement in at least one national daily newspaper].

(2) Subject to rule 13, any procurement exceeding [9] **[three million]** rupees shall be advertised on the website of the Authority, the website of the procuring agency, if any, and in at least two national daily newspapers of wide circulation, one in English and one in Urdu.

(4) A procuring agency shall ensure that the information posted on the website is complete for purposes for which it has been posted, and such information shall remain available on that website until the closing date for the submission of bids.

13. Exceptions.– The requirement of advertisement mentioned in rule 12, may be dispensed with after prior approval of the Authority in the following cases:

(a) the proposed procurement pertains to national security and its publication may jeopardize or compromise the objectives of national security; and

(b) the publication of advertisement or notice of the proposed procurement involves disclosure of information which is proprietary in nature or falls within the definition of intellectual property which is available from a single source.

14. Response time.– (1) The procuring agency may decide the response time for receipt of bids or proposals (including proposals for prequalification) from the date of publication of an advertisement or notice keeping in view the complexity of the procurement, availability and urgency but, in no circumstances, the response time shall be less

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9 The expression "two" substituted with the expression "three" vide Notification No. SO(Cab-I)2-9/2015 dated 17.08.2020

10 The expression "two" substituted with the expression "three" vide Notification No. SO(Cab-I)2-9/2015 dated 17.08.2020

than fifteen days for national competitive bidding and thirty days for international competitive bidding from the date of publication of advertisement or notice.

(2) All advertisements or notices shall expressly mention the response time allowed for the procurement along with the information for collection of bid documents which shall be issued till a given date, allowing sufficient time to complete and submit the bid by the closing date but the time limit shall not apply in case of an emergency procurement.

(3) The response time shall be calculated from the date of publication of the advertisement in a newspaper or on the website, whichever is later.

[10][**15. Framework contract**.–(1) A procuring agency may procure goods, services or works through framework contract in order to ensure uniformity in the procurement].

(2) The procuring agency shall adopt any of the methods of procurement mentioned in these rules for purposes of entering into a framework contract.

CHAPTER-IV

PREQUALIFICATION, QUALIFICATION, DISQUALIFICATION

AND BLACKLISTING

16. Prequalification.– (1) Subject to sub-rule (2), a procuring agency may, prior to floating the tenders or invitation to proposals or offers, engage in prequalification of bidders in case of services, civil works, turnkey projects and also in case of procurement of expensive and technically complex equipment to ensure that only technically and financially capable firms or persons having adequate managerial capacity are invited to submit bids.

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[10] Substituted vide Notification No. ADMN(PPRA)10-2/2014 dated 11.03.2014

(2) The procuring agency shall prequalify bidders under sub-rule (1) in case of procurement of goods of one hundred million rupees and above and large consultancy, except where a procuring agency, for reasons to be recorded in writing, dispenses with the requirement of prequalification of bidders.

(3) For purposes of the prequalification of bidders, a procuring agency shall take into consideration the following factors:

(a) qualifications;

(b) relevant experience and past performance;

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

(d) financial position;

(e) appropriate managerial capability; and

(f) any other factor that a procuring agency may deem relevant, not being inconsistent with these rules.

(4) The procuring agency shall ensure that the prequalification is based on the capacity of the interested parties to satisfactorily perform the services or works.

(5) In case of fast track projects where the time is the essence or where potential consultants are limited or the assignment is of a complex nature, the procuring agency may, after recording reasons and with the approval of Provincial Development Working Party, invite a request for proposals through public notice under rule 12.

[11][**(6)** Notwithstanding anything contained in sub-rules (1) and (2), Planning and Development Department of the Government may shortlist the individual consultants, firms or companies involving legal, financial and technical expertise].

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[11] Inserted vide Notification No. ADMN(PPRA)10-2/2014 dated 14.10.2014

[12][**(7)** A procuring agency may, at the time of prequalification process consider any of the individual consultants, firms or companies shortlisted under sub-rule (6), after conducting the due evaluation process (technical or financial), in case where:

(a) procuring agency lacks capacity of prequalification process;

(b) sufficient time to take up the process of prequalification is not available; and

(c) expertise acquired by individual consultant, firms or companies shortlisted under sub-rule (6) in line with the requirements of the procuring agency].

[13][**(8)** Planning and Development Department of the Government shall:

(a) before shortlisting process, in consultation with the key line departments, determine the parameters and selection criteria for shortlisting of individual consultants, firms or companies to be considered as consultant;

(b) shortlist all such individual consultants, firms or companies only for one financial year through its notified committee strictly in accordance with the procedure provided under these rules;

(c) shortlist atleast three individual consultants, firms or companies for each area of expertise;

(d) upload the list of such shortlisted individual consultants, firms or companies on the website of Punjab Procurement Regulatory Authority and Planning and Development Department of the Government for the consumption of public sector organizations; and

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12 Inserted vide Notification No. ADMN(PPRA)10-2/2014 dated 14.10.2014

13 Inserted vide Notification No. ADMN(PPRA)10-2/2014 dated 14.10.2014

(e) circulate the list to all the public sector organizations].

[14][**(9)** A procuring agency intending to use the facility of shortlisted individual consultants, firms or companies, while taking up the process of procurement, shall invite technical or financial bids from all such shortlisted individual consultants, firms or companies as per requirement of the procuring agency].

[15][**(10)** A procuring agency may select a consultant under this rule and where this rule is silent about any selection process, it shall adopt the selection process of a consultant provided in other rules].

[16][**(11)** Notwithstanding anything contained in these rules, the Government, on the recommendations of the Authority, may by notification direct that the organizations pre-qualified by an administrative department for the procurement mentioned in the notification, may be espoused by a procuring agency under the administrative control of that department or by such other department or procuring agency as mentioned in the notification];

17. Prequalification process.– (1) The procuring agency engaging in prequalification shall announce, in the prequalification documents, all information required for prequalification including instructions for preparation and submission of the prequalification documents, evaluation criteria, list of documentary evidence required by contractors to demonstrate their respective qualifications and any other information that the procuring agency deems necessary for prequalification.

(2)The procuring agency shall provide a set of prequalification documents to any contractor, on request and subject to payment of

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[14] Inserted vide Notification No. ADMN(PPRA)10-2/2014 dated 14.10.2014

[15] Inserted vide Notification No. ADMN(PPRA)10-2/2014 dated 14.10.2014

[16] in rule 16 after sub rule (10) the new sub rule (11) inserted vide Notification No. S.O(Cab-I)2-9/2015 dated 02.02.2017

such price as the procuring agency may determine to defray the cost on account of printing and provision of the document.

(3) The procuring agency shall promptly inform the contractor who has applied for the prequalification whether or not he has been prequalified and shall, on request from the applicant who had applied for prequalification, a list of contractors who have been prequalified.

(4) On a request, the procuring agency shall communicate to the contractor who has not been prequalified the reasons for not prequalifying the contractor.

(5) Only the prequalified contractors shall be entitled to participate in the subsequent procurement proceedings.

18. Qualification.– A procuring agency, at any stage of the procurement proceedings, having credible reasons for, or prima facie evidence of, any defect in the capacity or otherwise of a contractor, whether or not prequalified, may require the contractor to provide such further information concerning the professional, technical, financial, legal or managerial competence as the procuring agency may decide.

19. Disqualification.– The procuring agency shall disqualify a contractor on the ground that he had provided false, fabricated or materially incorrect information.

20. Declaration of ineligibility.– (1) Subject to rule 21, the procuring agency may, after providing an opportunity of hearing, declare, through a notification, an applicant for prequalification as ineligible for participating in any public procurement process of the organization for such period as it may determine on account of his engaging, directly or through an agent, in [17][**corrupt practice**].

(2) A copy of the notification shall be provided to the affected person and to the Authority.

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[17] The words "corrupt or fraudulent practice" substituted with the word "corrupt practice" vide Notification No.S.O(Cabinet-I)2-9/2015 dated 06.01.2016.

[18][**21. Blacklisting**.–(1) A procuring agency may, for a specified period, debar a bidder or contractor from participating in any public procurement process of the procuring agency, if the bidder or contractor has:

(a) acted in a manner detrimental to the public interest or good practices;

(b) consistently failed to perform his obligation under the contract;

(c) not performed the contract up to the mark; or

(d) indulged in any corrupt practice.

(2) If a procuring agency debars a bidder or contractor under sub-rule (1), the procuring agency:

(a) shall forward the decision to the Authority for publication on the website of the Authority; and

(b) may request the Authority to debar the bidder or contractor for procurement of all procuring agencies.

(3) The Managing Director may debar a bidder or contractor of any procuring agency from participating in any public procurement process of all or some of the procuring agencies for such period as the Managing Director may determine.

(4) Any person aggrieved by a declaration made under rule 20 or a decision under sub-rule (1) of this rule may, within thirty days from the date of the publication of the information on the website of the Authority, file a representation before the Managing Director and the Managing Director may pass such order on the representation as he may deem fit.

(5) Any person or procuring agency aggrieved by an order under sub-rule (3) or (4) may, within thirty days of the order, file a

[18] for rule 21 the above shall be substituted vide Notification No.S.O(Cabinet-I)2-9/2015 dated 06.01.2016.

representation before the Chairperson and the Chairperson may pass such order on the representation as he may deem appropriate.

(6) The mechanism or process for barring a bidder or contractor from participating in procurement process of a procuring agency, procuring agencies and a representation under this rule is specified in the Schedule appended to these rules];

CHAPTER-V

METHODS OF PROCUREMENT

[19][**22. Principal method of procurement**.– Save as otherwise provided hereinafter, the procuring agencies shall use open competitive bidding **or publication of request for tender** as the principal method of procurement for the procurement of goods, services and works].

23. Open competitive bidding.– Subject to rules 24 to 38, the procuring agencies shall engage in open competitive bidding if the cost of procurement is more than the prescribed financial limit.

24. Submission of bids.– (1) A bidder shall submit a bid in a sealed package or packages in such manner that the contents of the bid are fully enclosed and cannot be known until duly opened.

(2) A procuring agency shall specify the manner and method of submission and receipt of bids in an unambiguous and clear manner in the bidding documents.

25. Bidding documents.– (1) A procuring agency shall formulate precise and unambiguous bidding documents that shall be made available to the bidders immediately after the publication of the invitation to bid.

(2) For competitive bidding, whether open or limited, the bidding documents shall include the following:

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[19] in rule 22 after words "open competitive bidding", the words "or publication of request for tender" inserted vide Notification No.S.O(Cabinet-I)2-9/2015 dated 06.01.2016.

(a) invitation to bid;
(b) instructions to bidders;
(c) form of bid;
(d) form of contract;
(e) general or special conditions of contract;
(f) specifications and drawings or performance criteria (where applicable);
(g) list of goods or bill of quantities (where applicable);
(h) delivery time or completion schedule;
(i) qualification criteria (where applicable);
(j) bid evaluation criteria;
(k) format of all securities required (where applicable);
(l) details of standards (if any) that are to be used in assessing the quality of goods, works or services specified; and
(m) any other detail not inconsistent with these rules that the procuring agency may deem necessary.

(3) Any information that becomes necessary for bidding or for bid evaluation, after the invitation to bid or issue of the bidding documents to the prospective bidders, shall be provided in a timely manner and on equal opportunity basis.

(4) Where any change becomes essential in the procurement process, such change shall be made in a manner similar to that of the original advertisement.

(5) A procuring agency shall use standard bidding documents as and when notified under the regulations.

(6) Until the standard bidding documents are specified under the regulations, a procuring agency may use bidding documents already in use of the procuring agency to the extent they are not inconsistent with these rules.

(7) The procuring agency shall, on payment of such fee as the procuring agency may determine keeping in view the cost of printing and provision of the documents, provide a set of bidding documents to the prospective bidders.

26. Reservations and preference.– (1) A procuring agency shall allow all prospective 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 the policy of the Government.

(2) A procuring agency shall allow for a preference to domestic or national contractor in accordance with the policies of the Government and the magnitude of price preference to be accorded shall be clearly mentioned in the bidding documents under the bid evaluation criteria.

[20][**27. Bid security**.– The procuring agency may require the bidders to furnish a bid security not exceeding five per cent of the **estimated** price.

Explanation.- In this rule, the words 'estimated price' mean the price of procurement estimated by the procuring agency before initiation of the process of procurement].

28. Bid validity.– (1) A procuring agency, keeping in view the nature of the procurement, shall subject the bid to a bid validity period.

(2) The bids shall be valid for the period of time specified in the bidding document.

[21](3) "Subject to sub-rule (5), a procuring agency shall ordinarily be under the obligation to process and evaluate the bids within the stipulated bid validity period but, under exceptional circumstances and for reasons to be recorded in writing, if an extension is considered

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[20] In rule 27 substituted vide Notification No.S.O(Cabinet-I)2-9/2015 dated 06.01.2016.

[21] In rule 28 sub-rule (3) substituted vide Notification No. S.O(Cab-I)2-9/2015 dated 22.03.2019.

necessary, all the bidders shall be requested to extend their respective bid validity period but such extension shall not be for more than the original period of bid validity or 180 days whichever is more."

[22]"**(3A)** The sub-rule (3) shall be applicable with effect from 1st July 2018."

(4) A bidder who:

(a) agrees to the extension of the bid validity period shall also extend the validity of the bid bond or security for the extended period of the bid validity;

(b) agrees to the procuring agency"s request for extension of bid validity period shall not be permitted to change the substance of the bid; and

(c) does not agree to an extension of the bid validity period shall be allowed to withdraw the bid without forfeiture of the bid bond or security.

(5) The competent authority of the procuring agency shall not extend bid validity period without obtaining prior approval of the authority next above the competent authority and if the chief executive of an autonomous procuring agency is the competent authority then next higher authority in such a case shall be the board, syndicate or any other apex body of the procuring agency.

29. Extension of time for submission of bids.– If a procuring agency considers that it is necessary in public interest to extend the last date for the submission of the bids, it may, after recording reasons, do so in the manner similar to the original advertisement.

CHAPTER-VI

OPENING, EVALUATION AND REJECTION OF BIDS

30. Opening of bids.– (1) The date for opening of bids and the last date for the submission of bids shall be the same; and, bids shall be

[22] In rule 28 after sub-rule (3) the sub-rule (3A) inserted vide Notification No. S.O(Cab-I)2-9/2015 dated 22.03.2019.

opened at the time specified in the bidding documents which shall not be less than thirty minutes after the closing time for the submission of the bids.

(2) All bids shall be opened publicly in the presence of the bidders or their representatives who may choose to be present, at the time and place announced prior to the bidding and the procuring agency shall read aloud the unit price as well as the bid amount and shall record the minutes of the bid opening.

(3) All bidders in attendance at the time of opening of the bids shall sign an attendance sheet.

(4) The bids submitted after the closing time prescribed shall be rejected and returned without being opened.

[23][**31. Evaluation criteria**.– (1) A procuring agency shall formulate an appropriate evaluation criterion listing all the relevant information against which a bid is to be evaluated and such evaluation criteria shall form an integral part of the bidding documents.

(2) Failure to provide for an unambiguous evaluation criteria in the bidding documents shall amount to mis-procurement.

(3) In simple or standard procurement process like open competitive bidding or procurement through direct request for tender, the procuring agency may use the amount of the bid price as the sole evaluation criteria for the bids].

32. Evaluation of bids.– (1) All bids shall be evaluated in accordance with the evaluation criteria and other terms and conditions set forth in the prescribed bidding document.

(2) For purposes of comparison of the bids quoted in different currencies, the price shall be converted into a single currency specified in the bidding documents and the rate of exchange shall be the selling rate, prevailing on the date of opening of bids specified in the bidding documents, as notified by the State Bank of Pakistan on that day.

[23] in rule 31, after sub rule (2) the sub rule (3) inserted vide Notification No.S.O(Cabinet-I)2-9/2015 dated

6. 01.2016.

(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 issue of notice for invitation of bids.

33. Clarification of bids.– (1) No bidder shall be allowed to alter or modify his bid after the closing time for the submission of the bids.

(2) The procuring agency may, if necessary after the opening of the bids, seek and accept such clarifications of the bid as do not change the substance of the bid.

(3) Any request for clarification in the bid, made by the procuring agency and its response, shall invariably be in writing.

34. Discriminatory and difficult conditions.– Save as otherwise provided, no procuring agency shall introduce any condition, which discriminates between bidders or which is difficult to meet.

Explanation.- In ascertaining the discriminatory or difficult nature of any condition, reference shall be made to the ordinary practices of that trade, manufacturing, construction business or service to which that particular procurement is related.

35. Rejection of bids.– (1) The procuring agency may reject all bids or proposals at any time prior to the acceptance of a bid or proposal.

(2) The procuring agency shall upon request communicate to any bidder, the grounds for its rejection of all bids or proposals, but shall not be required to justify those grounds.

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

(4) The bidders shall be promptly informed about the rejection of the bids, if any.

[24][**(5) A procuring agency may, for reasons to be recorded in writing, restart bidding process from any prior stage if it is possible without violating any principle of procurement**

in rule 35, after sub rule (4) the sub rule (5) inserted vide Notification No.S.O(Cabinet-I)2-9/2015 dated 6. 01.2016.

contained in rule 4 and shall immediately communicate the decision to the bidders].

36. Re-bidding.– If the procuring agency rejects all the bids under rule 35, it may proceed with the process of fresh bidding but before doing that it shall assess the reasons for rejection and may, if necessary, revise specifications, evaluation criteria or any other condition for bidders.

[25][**36A. One person one bid**.- (1) In any procurement, one person may submit one bid and if one person submits more than one bids, the procuring agency shall reject all such bids.

(2) If a consortium of persons has submitted a bid in any procurement, it shall be construed that each member of the consortium submitted the bid].

37. Announcement of evaluation reports.– A procuring agency shall announce the results of bid evaluation in the form of a report giving justification for acceptance or rejection of bids at least ten days prior to the award of procurement contract.

38. Procedures for selection of contractors.– (1) Save as otherwise provided in these rules, single stage one envelope bidding procedure shall ordinarily be the main open competitive bidding procedure used for the procurement of works and standard goods.

(2) Other appropriate procedures for selection of contractors other than consultants may be adopted in the following circumstances:

(a) single stage two envelopes bidding procedure shall be used for procurement of such goods where the bids are to be evaluated on technical and financial grounds and the procedure for single stage two envelopes shall be:

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[25] after sub rule 36, rule 36A inserted vide Notification No. S.O(Cabinet-I)2-9/2015 dated 06.01.2016.

(i) the bid shall be a single package consisting of two separate envelopes, containing separately the financial and the technical proposals;

(ii) the envelopes shall be marked as "Financial Proposal" and "Technical Proposal";

(iii) in the first instance, the "Technical Proposal" shall be opened and the envelope marked as

"Financial Proposal" shall be retained unopened in the custody of the procuring agency;

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

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

(vi) after the evaluation and approval of the technical proposals, the procuring agency shall open the financial proposals of the technically accepted bids, publically at a time, date and venue announced and communicated to the bidders in advance, within the bid validity period;

[26][(vii) the financial proposal of the bids found technically non-responsive shall be retained unopened and shall be returned on the expiry of the grievance period or the decision of the

[26] in rule 38, in sub-rule (2), in clause (a), for sub-clause (vii), substituted vide Notification No. S.O(CAB-I)2-9/2015 dated 23.11.2017, published in the Punjab Gazette (Extraordinary), dated 30.11.2017.

complaint, if any, filed by the non-responsive bidder, whichever is later:

provided that the procuring agency may return the sealed financial proposal earlier if the disqualified or non-responsive bidder, contractor or consultant submits an affidavit, through an authorized representative, to the effect that he is satisfied with the proceedings of the procuring agency]; and

(viii) the lowest evaluated bidder shall be awarded the contract;

(b) two stage bidding procedure may 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 available to the procuring agency and the bidding procedure shall be:

First stage

(i) in the first instance, the bidders shall submit, according to the required specifications, a technical proposal without quoting price;

(ii) the technical proposal shall be evaluated in accordance with the specified evaluation criteria and may be discussed with the bidders regarding any deficiencies and unsatisfactory technical features;

(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) the procuring agency may revise or modify any aspect of the technical requirements or evaluation criteria, or it may add new requirements or criteria not inconsistent with these rules but any revisions or modifications shall be communicated to all the bidders at the time of invitation to submit final bids, and sufficient time shall be allowed to the bidders to prepare their revised bids but such time shall not be less than fifteen days in the case of national competitive bidding and thirty days in case of international competitive bidding;

(v) the bidders unwilling to conform their respective bids to the procuring agency"s technical requirements may withdraw from the bidding without forfeiture of their bid security;

Second stage

(i) the bidders, whose technical proposals or bids have not been rejected and who are willing to conform their bids to the revised technical requirements of the procuring agency, may submit a revised technical proposal along with the financial proposal;

(ii) the fresh and revised technical proposals and the financial proposals shall be opened at a time, date and venue announced and communicated to the bidders in advance but in setting the date for the submission of the revised technical proposals and financial proposals, a procuring agency shall allow

sufficient time to the bidders to incorporate the agreed changes in the technical proposal and prepare their financial proposals accordingly; and

(iii) the revised technical proposal and the financial proposal shall be evaluated in the manner prescribed above and the lowest evaluated bid shall be accepted;

(c) two stage two envelope bidding method shall be used for procurement where alternative technical proposals are possible, such as certain types of machinery or equipment or manufacturing plant and the procedure shall be:

First stage

(i) the bid shall comprise a single package comprising two separate envelopes containing the financial proposal and the technical proposal;

(ii) the envelopes shall be marked as "Financial Proposal" and "Technical Proposal";

(iii) in the first instance, the envelope marked "Technical Proposal" shall be opened and the envelope marked as "Financial Proposal" shall be retained unopened in the custody of the procuring agency;

(iv) the technical proposals shall be discussed with the bidders with reference to the procuring agency"s technical requirements;

(v) those bidders willing to meet the requirements of the procuring agency shall be allowed to

revise their technical proposals following these discussions; and

(vi) bidders not willing to conform to the technical proposal as per revised requirements of the procuring agency shall be allowed to withdraw

their respective bids without forfeiture of their bid security;

Second stage

(i) after agreement between the procuring agency and the bidders on the technical requirements, bidders who are willing to conform to the revised technical specifications and whose bids have not already been rejected shall submit a revised technical proposal and supplementary financial proposal, according to the technical requirement;

(ii) the revised technical proposal along with the original financial proposal and supplementary financial proposal shall be opened at a date, time and venue announced in advance by the procuring agency:

Provided that in setting the date for the submission of the revised technical proposals and supplementary price proposals a procuring agency shall allow sufficient time to the bidders to incorporate the agreed changes in the technical proposal and to prepare the required supplementary financial proposal; and

(iii) the procuring agency shall evaluate the whole proposal in accordance with the evaluation criteria and the lowest evaluated bid shall be accepted.

[27] [**38A.** Notwithstanding anything contained in these rules, the Government on the recommendations of the Authority, may by notification direct that the procurements mentioned in the notification may be made in the manner provided under rule 45 and in that case the expression „consultant" or „consultants" in that rule shall be deemed as „contractor" or „contractors" and the said rule shall be construed accordingly].

CHAPTER-VII

PROCUREMENT OF CONSULTANCY SERVICES

39. Rights and obligations.– The rights and obligations of the procuring agency and the consultant are governed by general and special conditions of contract signed between the procuring agency and the consultant.

40. Consultant Selection Committee.– Every procuring agency, for the selection of consultant, except for short consultancies, shall set up a Consultant Selection Committee of odd number members, which shall consist of the following:

(a) head of the procuring agency who shall be its chairperson.
(b) a nominee of the Planning and Development Department, a nominee of the Finance Department, as members; a representative of the procuring agency, as a member (secretary);
(c) the procuring agency may co-opt up to two members, having adequate technical knowledge and experience in the relevant field, for assistance in a given assignment that requires technical input.

41. Quorum.- Three members, including the chairman of the Consultant Selection Committee, shall form quorum for conducting the business of the Consultant Selection Committee.

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[27] after rule 38, new rule (38A) inserted vide Notification No. S.O(Cab-I)2-9/2015 dated 02.02.2017.

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42. Decision by simple majority.- All decision of the Consultant Selection Committee shall be made by majority of the members present and voting.

43. Functions and responsibilities of Committee.- The Consultant Selection Committee shall perform the following functions:

(a) short listing of consultants, responding to the expression of interest, where applicable, in accordance with the criteria mentioned in the expression of interest;

(b) approval of request for proposal before issuance;

(c) evaluation of technical and financial proposals, according to the selection method and evaluation criteria, mentioned in the request for proposal, and in accordance with the provisions of these rules; and

(d) finalization of recommendation for selection of consultants based on evaluation criteria.

44. Selection of consultants.– Depending upon the selection method, the procuring agency shall include, among others, the following steps in the process of selection of a consultant:

(a) preparation and approval of the terms of reference of the assignment;

(b) preparation of the cost estimate or budget of the assignment;

(c) public advertisement of invitation of consultants" expressions of interest and their short-listing;

(d) preparation and issuance of the request for proposal to the shortlisted consultants;

(e) preparation and submission of proposals by the consultants;

(f) evaluation of technical proposals; and

(g) opening and evaluation of financial proposals.

45. Methods for selection of consultants.- (1) A procuring agency may utilize one of the methods mentioned in succeeding sub-rules for selection of a consultant.

(2) Least Cost Selection: This is the preferred method for selecting consultants for assignments of standard or routine nature such as audit, simple engineering design or supervision of noncomplex works, where the well-established practices and standards exist.

(3) Quality and Cost Based Selection: This method may be used where:

(a) quality is the prime consideration while cost is a secondary consideration;

(b) terms of Reference are well defined;

(c) the financial proposals of only those technically responsive bidders who obtained minimum sixty five percent marks shall be opened;

(d) a combined evaluation of the technical and financial proposals is carried out by weighting and adding the quality and the cost scores;

(e) the weight for quality is normally of eighty percent with twenty percent given to cost and more than twenty percent weight to the cost of the services is

justified only in relatively routine and straightforward assignments (such as design of simple structures), whereas in no cases it should exceed thirty percent and the consultant obtaining the highest combined score is invited for negotiations;

(4) Quality Based Selection: This system may be used for highly specialized, innovative and complex assignments, where quality is the predominant factor.

[28][(5) Subject to sub-rule (6), a procuring agency may, in a complex project, engage, through direct contracting, an organization owned or controlled by the Government, the Federal Government or any other Provincial Government with the prior approval of:

(a) Provincial Development Working Party (PDWP) of Planning and Development Department in case of the administrative departments or attached departments or agencies of the Government]; and

(b) PDWP and the governing body, by whatever name called, in case of an autonomous body, company, authority or institution.

(6) In case of engagement of an organization under sub-rule

(5), the procuring agency shall:

(a) record reasons in writing for direct contracting and shall issue a certificate of reason-ability of the negotiated price of consultancy based on the principles of procurement contained in rule 4; and
(b) obtain approval of the Authority to the extent of declaring the project as complex project.

(7) A procuring agency may, after recording reason in writing, use any method for selection of consultant other than least cost selection.

46. Selection process of individual consultant.- The following

shall be the selection process of individual consultant [29][**in a short consultancy**]:

(a) individual consultant may not be required to submit proposals and shall be selected based on the qualifications and experience for the assignment;

[28] in rule 45, for sub-rule (5), substituted vide Notification No. SO(CAB-I)2-9/2015, dated 30.08.2017, published in the Punjab Gazette (Extraordinary), dated 13.09.2017.

[29] after the words "selection process of individual consultant" the words "in a short consultancy" inserted vide Notification No.S.O(Cabinet-I)2-9/2015 dated 06.01.2016.

(b) individual consultant shall be selected by comparing the qualifications and experience of at least three consultants among those who have expressed interest in the assignment or have been approached directly by the procuring agency;

(c) individual consultant considered for the comparison of qualifications and experience shall meet the minimum relevant qualifications, and the one selected to be employed by the procuring agency shall be the best qualified and shall be fully capable of carrying out the assignment;

(d) individual consultant may be selected on a single-source basis (with due justification) in exceptional cases such as an emergency situation resulting from a natural disaster or where the individual is the only consultant qualified for the assignment;

(e) for key assignments, interviews may be set up, if required.

[30] [**46A Selection process of firm of consultants:** The following shall be the selection process of a firm of consultants in a short consultancy for purposes such as third party validation, bid evaluation, terms of reference, preparation of documents relating to prequalification and request for proposal, pre-shipment inspection, audit, simple engineering design or supervision of non-complex work, where the cost of consultancy does not exceed three million rupees:

(a) the firm shall be selected by considering at least three quotations from renowned, registered and well reputed firms on the basis of qualification and experience for the assignment;

(b) the firm considered for the comparison of qualification and experience shall meet the minimum relevant qualification

[30] after rule 46 new rule (46A) inserted vide Notification No. S.O(Cab-I)2-9/2015 dated 02.03.2017

and the one selected to be employed by the procuring agency shall be the best qualified and fully capable of carrying out assignment; and

(c) the procuring agency may conduct interviews for the selection of best option].

47. Expression of interest.- (1) A request for expression of interest shall be advertised in accordance with the provisions of rule

12 and rule 13.

(2) The expression of interest shall contain the following information:

(a) the name and address of procuring agency;

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

(c) closing date and place of the submission of the expression of interest;

(d) criteria for short listing or prequalification where required; and

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

48. Request for proposals.– (1) A procuring agency shall use a request for proposal for seeking proposals from the shortlisted or pre-qualified consultants which shall include the following:

(a) letter of invitation: the letter of invitation shall mention the name and address of the procuring agency and its intention 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 may help them prepare responsive proposals;

(c) terms of reference: the terms of reference shall unambiguously define the objectives, goals and scope of the assignment, core team of required experts, expected deliverables with timelines and list of services necessary to carry out the assignment;

(d) evaluation criteria: except as otherwise provided, the evaluation of proposals shall be carried out giving due consideration to quality and cost;

(e) type of contract: a procuring agency, depending on the circumstances, may use one of the following types of contracts:

(i) lump sum contract shall be used mainly for assignments in which the content, 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 shall be used for small projects, especially when the assignment is for less than a month; and

(iv) any other, based on combination of the above and including out of pocket expenses, where required;

(f) special provisions: a procuring agency may specify any other requirement related to the assignment or contract, where required.

(2) A procuring agency shall invite the prospective consultants to submit their technical and financial proposals in separately sealed envelopes and the procuring agency shall give deadline for submission of proposals but the consultants shall be given adequate time to prepare their proposals which shall not be less than two weeks.

[31][**49.** **********]

50. Evaluation of quality of consulting services.– Evaluation criteria for technical evaluation of consultants shall include the following:

(a) experience: the consultants specialized skills, working on the similar assignment and access to particular technologies related to the assignment;

(b) financial capability: financial capability of the consultant may be evaluated with a view to ensuring that the consultant can complete the assigned task in a timely manner;

(c) approach and methodology: the methodology proposed by the consultants shall be evaluated for its innovativeness and soundness;

(d) quality management: the availability of a well-established quality management system may be taken into account for large and complex assignments; and

(e) staff proposed: qualification and experience of the proposed staff of the consultant in the relevant field.

51. Association of consultants.– (1) An association of consultants may take either the form of a joint venture or a subcontract and such association may participate in procurement process with the permission of the procuring agency.

(2) Under a joint venture, all members, if awarded the contract, shall individually sign and be jointly and severally liable for the entire assignment and such an association may be known as a consortium, association or joint venture.

[31] rule 49 omitted vide Notification No.S.O(Cabinet-I)2-9/2015 dated 06.01.2016.

52. 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.

53. Negotiations.– (1) Notwithstanding the provision under rule 57, the procuring agency may negotiate with the highest ranked bidder for consultancy regarding methodology, work plan, staffing, contract price and special conditions of the contract.

(2) In case of failure of negotiations, the procuring agency may invite the next ranked bidder.

(3) A committee of the procuring agency shall negotiate with the consultant and negotiation by a single person on behalf of the procuring agency shall not be allowed.

54. Professional liability of consultant.– (1) The consultant selected and awarded a contract shall be liable for consequence of errors or omissions on the part of the consultant.

(2) The extent of liability of the consultant shall form part of the contract and such liability shall not be less than remunerations nor it shall be more than twice the remunerations.

(3) The procuring agency may demand insurance on part of the consultant to cover the liability of the consultant and necessary costs shall be borne by the consultant.

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

CHAPTER-VIII

ACCEPTANCE OF BIDS AND AWARD OF CONTRACTS

55. Acceptance of bids.– Subject to these rules, the bidder with the lowest evaluated bid, if not in conflict with any other law, shall be

awarded the procurement contract within the original or extended bid validity period.

[32] [**55A. Single complying proposal**.- Subject to rule 35, if one complying bid is received, the procuring agency may award the contract to the bidder].

56. Performance guarantee.– Where needed and clearly expressed in the bidding documents, the procuring agency shall require the successful bidder to furnish a performance guarantee which shall not exceed ten percent of the contract amount.

57. Limitation on negotiations.– (1) Save as otherwise provided in these rules, a procuring agency shall not negotiate with any of the bidders.

(2) In case of goods of highly technical nature, the procuring agency shall ensure that the bidders submit the revised financial bids immediately after opening of the technical bids in the same manner as the earlier financial bids were submitted and the procuring agency shall not allow extra time for submission of revised financial bids by the bidders.

(3) In this rule, the expression „goods of highly technical nature" means all goods including machinery, its parts and micro-components, industrial, scientific or electronic equipment, plant and tools which are sophisticated in nature costing more than fifty million rupees and procured by adopting the two stages-two envelope procurement procedures.

58. Confidentiality.– The procuring agency shall keep all information regarding the bid evaluation confidential until the time of the announcement of the evaluation report.

59. Alternative methods of procurements.– A procuring agency may utilize the following alternative methods of procurement of goods, services and works:

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[32] after rule 55 rule 55A inserted vide Notification No.S.O(Cabinet-I)2-9/2015 dated 06.01.2016.

(a) petty purchases: a procuring agency may engage in petty purchases where the object of the procurement is below the

financial limit of [33] [**seventy five**] thousand rupees and such procurement shall be exempted from the requirements of bidding or quotation of prices; the procuring agency shall, however, ensure that procurement of petty purchases is in conformity with the principles of procurement;

(b) petty purchases through quotation: a procuring agency may engage in petty purchases through at least three quotations

where the cost of the procurement is more than [34] [**seventy five**] thousand rupees but less than [35][**two**] hundred thousand rupees and such procurement shall be exempted from the requirements of bidding procedures; the procuring agency shall, however, ensure that such procurement is in conformity with the principles of procurement;

(c) direct contracting: a procuring agency shall only engage in direct contracting if any of the following conditions exist:

(i) the procurement concerns the acquisition of spare parts or supplementary services from original manufacturer or supplier when the same are not available from alternative sources;

(ii) only one manufacturer or supplier exists for the required procurement but in such a case, the procuring agency shall specify the appropriate fora which may authorize procurement of proprietary object after due diligence; and

(iii) where a change of supplier may result in acquisition of material having different technical specifications or

characteristics that may cause incompatibility or disproportionate technical difficulties in operation and

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[33] The expression "fifty" substituted with the expression "seventy five" vide Notification No. SO(Cab-I)2-9/2015 dated 17.08.2020

[34] The expression "fifty" substituted with the expression "seventy five" vide Notification No. SO(Cab-I)2-9/2015 dated 17.08.2020

[35] The expression "one" substituted with the expression "two" vide Notification No. SO(Cab-I)2-9/2015 dated 17.08.2020

maintenance; and the contract does not exceed three years in duration;

(iv) repeat orders not exceeding fifteen percent of the original procurement;

(v) in case of an emergency but the procuring agency shall specify appropriate fora vested with necessary authority to declare an emergency;

(vi) when the price of goods, services or works is fixed by the Government or any other authority, agency or body under the law; and

(vii) for purchase of motor vehicle from local original manufacturers or their authorized agents at manufacturer"s price.

(d) negotiated tendering: a procuring agency may engage in negotiated tendering with one or more contractors with or without prior publication of a procurement notification but this procedure shall only be used when:

(i) the supplies involved are manufactured purely for the purpose of supporting a specific piece of research or an experiment, a study or a particular development;

(ii) for technical or artistic reasons, or for reasons connected with protection of exclusive rights or intellectual property, the supplies may be manufactured or delivered only by a particular supplier;

(iii) for reasons of extreme urgency brought about by events unforeseeable by the procuring agency, the time limits laid down for open and limited bidding methods cannot be met, however, the circumstances invoked to justify extreme urgency must not be attributable to the procuring agency; and

(iv) the Provincial Cabinet, for reason to be recorded in writing, approves any specific procurement to be made on urgent basis and shall fix the time for such urgency.

60. Unsolicited proposal.– In case of unsolicited proposal received for any engineering, procurement and construction project involving cost of one **thousand** million rupees and above, the procuring agency shall process the proposal to ascertain its viability and after such process if the proposal is found viable, the procuring agency:

(a) shall advertise the proposal for open competition without disclosing the name of the initiator of unsolicited proposal;
(b) shall conduct prequalification process;
(c) shall exempt the initiator of the unsolicited proposal from the prequalification;
(d) if no other bidder in response to the advertisement submits bid, the procuring agency may award the contract to the initiator of the proposal;
(e) in case of bidding competition, the initiator of the proposal shall be given first right of refusal if the initiator does not emerge as the lowest bidder; and
(f) shall award five percent additional weightage to the initiator of the proposal from the combined score of technical and financial evaluation.

[36][**61. Exemption**.– (1) The Government or the Board shall not **relax** application of these rules for procurement of services.

(2) A procuring agency may directly procure goods from a public sector manufacturing unit on fixed price or negotiated price where value of procurement does not exceed one million rupees.

(3) Where value of goods exceeds one million rupees or in a competitive bidding, the public sector manufacturing unit participating

[36] in sub rule (1) the word "exempt" substituted with the word "relax", sub rule (2) and (3) substituted and sub rule (4) inserted vide Notification No.S.O(Cabinet-I)2-9/2015 dated 06.01.2016.

in the bid may, within three working days of opening of the bids, match the lowest evaluated bid.

(4) In this rule, public sector manufacturing unit means a manufacturing unit owned or controlled by the Government, Federal Government, local government or by an organization which is owned or controlled by any of these Governments and enlisted on the website of the Authority].

62. On account payments.– A procuring agency shall make prompt payments to the contractor against the invoice or running bill on satisfactory performance within the time given in the conditions of the contract which shall not exceed thirty days.

63. Commencement of procurement contract.– A procurement contract shall come into force:

(a) where no formal signing of a contract is required, from the date the notice of the acceptance of the bid or purchase order has been given to the bidder whose bid has been accepted and such notice of acceptance or purchase order shall be issued within a reasonable time; or

(b) where the procuring agency requires signing of a written contract, from the date on which the signatures of both the procuring agency and the successful bidder are affixed to the written contract and such affixing of signatures shall take place within a reasonable time; and

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

64. Closing of contract.– (1) Except for defect liability by the contractor, as specified in the conditions of contract, performance of the contract shall be deemed close on the issue of overall delivery certificate or taking over certificate which shall be issued within thirty

days of final taking over of goods or receiving the deliverables or completion of works enabling the contractor to submit final bill.

(2) In case of defect liability, defect liability certificate shall be issued within thirty days of the expiry of the said period enabling the contractor to submit the final bill, except for unsettled claims, which shall be settled through resolution of dispute mechanism provided in the contract.

[37][**64A. Assignment.**- A procuring agency may assign whole or part of procurement process to another procuring agency with the consent of that other procuring agency].

CHAPTER-IX

MAINTENANCE OF RECORD AND FREEDOM OF INFORMATION

65. Record of procurement.– (1) A procuring agency shall maintain a record of a procurement along with all associated documents 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.

66. Public access and transparency.– (1) As soon as a contract has been awarded, the procuring agency shall make all documents related to the evaluation of the bid and award of contract public.

(2) Where the disclosure of any information related to the award of a contract is of proprietary nature or where the procuring agency is convinced that such disclosure shall be against the public interest, it may withhold only such information from public disclosure subject to the prior approval of the Authority.

CHAPTER-X

REDRESSAL OF GRIEVANCES AND SETTLEMENT OF DISPUTES

67. Redressal of grievances by the procuring agency.– (1) The procuring agency shall constitute a committee comprising of odd

[37] after rule 64, the rule 64A inserted vide Notification No.S.O(Cabinet-I)2-9/2015 dated 06.01.2016.

number of persons, with proper powers and authorizations, to address the complaints of bidders that may occur prior to the entry into force of the procurement contract.

(2) Any bidder feeling aggrieved by any act of the procuring agency after the submission of his bid may lodge a written complaint concerning his grievances not later than [38] [**ten**] days after the announcement of the bid evaluation report.

(3) The committee shall investigate and decide upon the complaint within fifteen days of the receipt of the complaint.

(4) Mere fact of lodging of a complaint shall not warrant suspension of the procurement process.

68. Arbitration.– (1) After coming into force of the procurement contract, disputes between the parties to the contract shall be settled through mediation or arbitration.

(2) The procuring agency shall provide for a method of mediation or arbitration or both in the procurement contract.

69. Mis-procurement.– Any violation of these rules shall be treated as mis-procurement.

70. Repeal.– The Punjab Procurement Rules, 2009 issued vide notification No.MD(PPRA)2-1/2010 are hereby repealed.

[38] substituted vide Notification No. ADMN(PPRA)10-2/2014 dated 11.03.2014

[39][SCHEDULE

{see sub-rule (6) of rule 21}

BLACKLISTING MECHANISM OR PROCESS

1. The procuring agency may, on information received from any resource, issue show cause notice to a bidder or contractor.
2. The show cause notice shall contain:

   (a) precise allegation, against the bidder or contractor;
   (b) the maximum period for which the procuring agency proposes to debar the bidder or contractor from participating in any public procurement of the procuring agency; and
   (c) the statement, if needed, about the intention of the procuring agency to make a request to the Authority for debarring the bidder or contractor from participating in public procurements of all the procuring agencies.

3. The procuring agency shall give minimum of seven days to the bidder or contractor for submission of written reply of the show cause notice.
4. In case, the bidder or contractor fails to submit written reply within the requisite time, the procuring agency may issue notice for personal hearing to the bidder or contractor/ authorize representative of the bidder or contractor and the procuring agency shall decide the matter on the basis of available record and personal hearing, if availed.
5. In case the bidder or contractor submits written reply of the show cause notice, the procuring agency may decide to file the matter or direct issuance of a notice to the bidder or contractor for personal hearing.
6. The procuring agency shall give minimum of seven days to the bidder or contractor for appearance before the specified officer of the procuring agency for personal hearing.
7. The procuring agency shall decide the matter on the basis of the available record and personal hearing of the bidder or contractor, if availed.

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[39] Schedule added after rule 70 vide Notification No.S.O(Cabinet-I)2-9/2015 dated 06.01.2016.

8. The procuring agency shall decide the matter within fifteen days from the date of personal hearing unless the personal hearing is adjourned to a next date and in such an eventuality, the period of personal hearing shall be reckoned from the last date of personal hearing.

9. The procuring agency shall communicate to the bidder or contractor the order of debarring the bidder or contractor from participating in any public procurement with a statement that the bidder or contractor may, within thirty days, prefer a representation against the order before the Managing Director of the Authority.

10. The procuring agency shall, as soon as possible, communicate the order of blacklisting to the Authority with the request to upload the information on its website.

11. If the procuring agency wants the Authority to debar the bidder or contractor from participating in any public procurement of all procuring agencies, the procuring agency shall specify reasons for such dispensation.

12. The Authority shall immediately publish the information and decision of blacklisting on its website.

13. In case of request of a procuring agency under para 11 or representation of any aggrieved person under rule 21, the Managing Director shall issue a notice for personal hearing to the parties and call for record of proceedings of blacklisting. The parties may file written statements and documents in support of their contentions.

14. In case of representation of any aggrieved person or procuring agency under rule 21, the Chairperson shall issue a notice for personal hearing to the parties and may call for the record of the proceedings. The parties may file written statements and documents in support of their contentions.

15. In every order of blacklisting under rule 21, the procuring agency shall record reasons of blacklisting and also reasons for short, long or medium period of blacklisting.

16. The Authority shall upload all the decisions under rule 21, available with it, on its website. But the name of a bidder or

contractor shall immediately be removed from the list of blacklisted persons on expiry of period of blacklisting or order of the competent authority to that effect, whichever is earlier.

17. An effort shall be made for electronic communication of all the notices and other documents pursuant to this mechanism or process].

CHIEF SECRETARY

GOVERNMENT OF THE PUNJAB

10.2 ANNEXURE-02 – DELIGATION OF FINANCIAL POWER RULES 2006

https://finance.punjab.gov.pk/system/files/FinancialPowerRules2006.pdf

10.3 ANNEXURE-03 – DRUG RULES 1986

The Drugs (Labelling and Packing) Rules, 1986

The Drugs (Labelling and Packing) Rules, 1986

2. Short title and commencement: (1) These rules may be called the Drugs (Labelling and Packing) Rules, 1986.
(3) They shall come into force on the expiration of the period of one year beginning with their publication in the official Gazette.

3. 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).

4. Manner of labelling: The following particulars shall appear either in print or in writing in inedible ink in a conspicuous manner on the label of the innermost container of a drug and also on the covering in which such container is packed, namely :--

(n) the registered name of the drug;
(o) 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 breakets with at least equal prominence as that of the brand name;
(p) 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,--

b in the case of oral liquid preparations, in terms of contents per specified volume,, the volume being indicated in millilitres;
c in the case of liquid parenteral preparations ready for administration, in terms of millilitres 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 warpper affixed to any package in which such ampoule is issued for sale:

(p) 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;
(q) 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

3 in the case of other preparations, in terms of percentage by weigh or volume or unit age, per gram or milliliter, as the case may be;

(u) the name and principle place of business of the manufacturer;
(v) the drug manufacturing licence number;

(w) the drug registration number;

(x) the date of expiry;
(y) Urdu version of the following namely:-

(z) registered name of drug.
b dosage (numerals in English shall be sufficient): and

c 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 b lister or foil, or contained in an ampoule of a capacity of not more than two millilitres 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.

(bb) Labelling of drugs for internal use: The label of container of a drug meant for internal use, except a drug contained in a strip or foil or blister or collapsible tube, shall, in addition to the particulars required to be given under rule 3, bear in a conspicuous manner,--

4 If it contains a substance specified in the Schedule, the words "To be sold on prescriptions of a registered medical practitioner only"; and

5 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.

(3) Labelling of drugs for external use only: The label of a container of ointment, cream, liniment, lotion, liquid, antiseptic or any other drug for external application shall, in addition to the particulars required to be given under rule 3, bear in a conspicuous manner,--

(i) the words "For external use only"; and

(ii) if the drug contains a substance specified in the Schedule, the words "Poison; for external use only".

(4) Labelling of physician's samples: The label of a container of every drug intended for distribution to the medical profession as free sample shall, in addition to the particulars required to be given under these rules, bear the words "Physician's sample: Not for sale" which shall be overprinted or stamped: Provided that if the drug is packed in a strip of paper or blister or foil or contained in an ampoule of a capacity of not more than three millilitres or in a collapsible tube, it shall be sufficient to label the outer packing only with the said words.

(5) Labelling of drugs for Government supply: The label of a container of every drug intended for the supply to any Government agency including an autonomous body or a semi-Government Agency shall, while complying with the other labelling requirements of these rules, bear the words or mark reading "Government Supply" or such other words or mark as may be required by the agency concerned.

(6) Labelling 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 use only.

6. Outer transparent wrapper not to require labelling: Nothing in these rules shall be deemed to require the labelling of any transport cover, wrapper, case or other covering used solely for the purpose of packing, transport or delivery of a drug.

7. Labelling of non-sterile surgical ligature and suture: Every container of, and every wrapper enclosing a surgical ligature or suture, other than a ligature or suture certified to be sterile and fit for surgical use without further sterilization, shall bear a label on which shall be printed or written in a conspicuous manner in indelible red ink the word

"Non-sterile surgical ligature/suture: Not to be used for operation upon human body unless properly sterilized".

8. Use of letter to indicate specifications: If a drug is included in the recent edition of any publication specified in the rules, the name of relevant publication in conventional abbreviations (B.P., U.S.P., etc.) shall be printed in indelible ink, on the label to indicate that the drug conforms to the specifications set out in that publication.
9. Packing of finished drugs: Each finished drug ready of use-shall be packed in containers intended for retail sale to a hospital, .dispensary, clinic or any other such institution.
10. Labelling 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 labelled in accordance with rule 23 of the Drugs (Licensing, Registering and Advertising) Rules. 1976.

6 Labelling 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,--

8. name of drugs ;

9. name and address of manufacturer; and
10. 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 millilitres 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.

10. Exemption: These rules shall not be applicable in respect of a drug made up ready for treatment, whether after or without dilution and is supplied by a person licensed to sell drugs on the prescription of a registered medical practitioner.

Provided that the label bears the following particulars, namely :--

2 te ham e and address of the suppliers of the drug;

3 the name of the patient ;
4 the number representing the serial number of the entries in the prescription register;

5 if the drug is for internal use, the dosage;

6 if the drug is for external use, and does not contain a substance specified in the Schedule' the words "For external use only"; and

7 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

12. C.N.S. stimulants.

13. Drugs affecting uterine motility.
3, Drugs inhibiting hormonal production.

8 Hormones and other steroidal preparation excluding preparations for external and topical use.
(3) Narcotic drugs as per Single Convention on Narcotic Drugs, 1961.

(4) Psychotropic substances mentioned as per Convention on Psychotropic Substances, 1971.

DRUGS (LICENSING, REGISTERING AND ADVERTISING) RULES, 1976

S.R.O. 145 (I)/76 dated 12th February 1976:- In exercise of the powers conferred by Section 41 of the Drugs Ordinance, 1976 (IV of 1976), the Federal Governme nt is pleased to make the following rules, namely :--

CHAPTER I - PRELIMINARY

2 Short title and commencement: .(1) These rules may be called the Drugs (Licensing, Registering and Advertising) Rules, 1976.
(2) They shall come into force at once.

3 Definitions.-- In these rules, unless there is anything repugnant in the subject or context:--

14. "active pharmaceutical ingredient" means a substance or compound that is intended to be used in the manufacture of a pharmaceutical product as a pharmacologically a ctive compound (ingredient);
15. "airlock" means an enclosed space with two or more doors, which is interposed between two or more rooms of differing classes of cleanliness for the purpose of controlling the airflow between those rooms when they need to be entered and an airlock is designed for and used by either people or goods;
16. "authorized person" means a person responsible for the release of batches of product for sale;
17. "basic manufacture" means manufacture of a drug from basic raw material to a product which is ready for use as a starting material for the formulation of a finished drug or for repacking and such manufacture may involve chemical, bio-chemical, photochemical, microbial or such other processes or a combination of any of such processes;
18. "batch (or lot)" means a defined quantity of starting material, packaging material, or finish product processed in a single process or series of processes so that it could be expected to be homogeneous in the case of continuous manufacture the batch must correspond to a defined fraction of the production, characterized by its intended homogeneity, and to complete certain stages of manufacture it may sometimes be necessary to divide a batch into a number of sub-batches, which are later brought together to from a final homogeneous batch;
19. "batch number (or lot number)" means a distinctive combination of numbers and or letters which specifically identifies a batch on the labels, the batch records, the certificates of analysis, and that permit the production history of the batch to be traced and revived.
20. "batch numbering system" means a standard operating procedure describing the details of the batch numbering;

2 "batch records" means all documents associated with the manufacture of a batch of bulk product or finished product showing a history of each batch of product and of all circumstances pertinent to the quality of the final product;

3 "biological agents" means micro-organisms, including genetically engineered micro-organisms, cell cultures and endoparasites, whether pathogenic or not;

4 "bulk product" means any product that has completed all processing stages up to, but not including, final packaging;

5 "calibration" means the set of operations that establish, under specified conditions, the relationship between values indicated by a instrument or measuring system for especially weighing, recording and controlling, or the values represented by a material measure and the corresponding known values of a reference standard and the limits for acceptance of the results of measuring;

6 "clean area" means an area with defined environmental control of particulate and microbial contamination, constructed and used in such a way as to reduce and or eliminate introduction, generation and retention of contaminants within the area;

7 "compounding" means scientific combination of two or more ingredients with a view to make a finished drug;

8 "consignment or delivery" means the quantity of starting material or of a drug product, made by one manufacturer and supplied one time in response to a particular request or order, a consignment may comprise one or more packages or containers and may include material belonging to more than one batch;

9 "critical process" means a process that may cause variation in the quality of the pharmaceutical product;

10 "cross-contamination" means contamination of a staring material intermediate product, or finished product with another starting material or drug during production;

11 "finished product" means a product that has undergone all stages of production, including packaging in its final container and labeling;

12 "Form" means a form set forth in Schedule A;

13 "formulation" means all operations involved in converting a drug into a final pharmaceutical dosage form ready for use as a finished drug including compounding, processing, formulating, filling, packing, finishing, labelling and other like processes;

14 "good manufacturing practices for pharmaceutical products" means part of quality assurance which:--

15. ensure that products are consistently produced and controlled to the quality standards appropriate to their intended use are as required by the marketing authorization or product specification; and

11 diminish the risks, inherent in any pharmaceutical production, including contamination, cross contamination and mix ups (confusion) that cannot be detected completely through the testing of final products;

(4) "half-finished product" means any material or mixture of materials that has to undergo further manufacture;

(3) "in-process control" means checks performed during production in order to monitor and if necessary to adjust the process to ensure that the product conforms to its specifications and control of the environment or equipment may also be regarded as a part of in -process control;

(4) "intermediate product" means partly processed material that must undergo further manufacturing steps before it becomes a bulk product;

(5) "large-volume parenterals" means sterile solutions intended for parenteral application with a volume of more than 100ml in one container of the finished dosage form;

(6) "manufacture" means all operations of production, quality control, release, storage and the related controls;

(7) "manufacturer" means a company that carries out at least one step of manufacture;

17. "marketing authorization" means a document, issued by the Drug Registration Board set up under the Drugs Act, 1976, as a certificate of drug registration;

(ab) "master formula" means a document or set of documents specifying the starting materials with their quantities and the packaging materials, together with a description of the procedure and precautions required to produce a specified quantity of a finished product as well as the processing instructions, including the in-process controls;

(ac) "master record" means a document or set of documents that serve as a basis for the batch documentation (blank batch record);

(ad) "new drug" means a drug that has not been commonly sold or distributed to the public in Pakistan and is introduced for the first time;

(ae) "Ordinance" means the Drugs Ordinance, 1976 (IV of 1976);

(af) "packaging" means all operations, including filling and labelling which a bulk drug has to undergo in order to become a finished product;

Note: Sterile filling would not normally be regarded as part of packaging, the bulk product being the filled, but not the finally packaged, primary container.

(ag) "packaging material" means any material, including printed material, employed in the packaging of a pharmaceutical product, excluding any outer packaging used for transportation or shipment and packaging materials are referred to as primary or secondary according to whether or not they are intended to be in direct contact with the product;

(ah) "pharmaceutical product" means any drug intended for human use or veterinary use presented in its finished dosage form or as a starting material for use in such a dosage form;

(ai) "processing instructions or procedures" means a defined in clause (ab) of this section;

(aj) "production" means all operations involved in the preparation of a pharmaceutical product, from receipt of materials, through processing and packaging, to its completion as the finished product;

(ak) "purity" means the degree to which other chemical or biological entities are present in any substance;

(al) "quality assurance" means the totality of the arrangements made with the object of ensuring that pharmaceutical products are of the quality required for their intended use and so incorporates good manufacturing practices, Quality Control and other factors including product design and development and good laboratory practices;

(am) "quality control" means the part of good manufacturing practices concerned with sampling, specifications, and testing as well as the organization, documentation, and release procedures which ensure that the necessary and relevant tests are actually carried out and that materials are not released for use, nor finished products released for sale or supply until their quality has been judged to be satisfactory and it is involved in all decisions concerning the quality of the product;

(an) "quarantine" means status of starting or packaging materials intermediate, or bulk or finished products isolated physically or by other effective means while a decision is awaited on their release, rejection, or reprocessing;

(ao) "reconciliation" means a comparison, making due allowance for normal variation between the amount of product or materials theoretically produced or used and the amount actually produced or used;

(ap) "recovery or blending" means the introduction of all or part of previous batches, or of redistilled solvents and similar products, of the required quality into another batch at a defined stage of manufacture;

(aq) "repacking" means all operations involved in the transfer of a drug from a larger container or packing into smaller containers or packings including filling, packing and labeling with a

view to make it ready for retail sale or wholesale, but does not includes any compounding, or processing with a view to formulate it in any dosage form;

(ar) "retail sale" means a sale other than wholesale;

(as) "reprocessing" means the reworking of all or part of a batch of product of an unacceptable quality from a refined stage of production so that its quality may be rendered acceptable by one or more additional operations;

(at) "returned product" means finished product sent back to the manufacturer or distributor;

(au) "Schedule" means Schedule to these rules;

(av) "semi-basic manufacture" means manufacture from an intermediate substance of a drug to be used as a starting material for the formulation of a finished drug or to be used for repacking;

(aw) "specification" means the requirements with which the products or materials used or obtained during manufacture must conform as specified in the Drugs (Specification) Rules, 1978;

(ax) "standard operating procedure" means an authorized written procedure indicating instructions for performing operations not necessarily specific to a given product or material but of a more general nature such as equipment operation, maintenance and cleaning validation, cleaning of premises and environmental control sampling and inspection, and certain standard operating procedures may be used to supplement product specific master and batch production documentation;

ay) "starting material" means any substance used in the production of a pharmaceutical product but excluding packaging materials;

(az) "system" means a regulated pattern of interacting activities and techniques which are united to form an organized whole;

(ba) "validation" means the documented act of proving that any procedure, process, equipment, material, activity or system works correctly and actually leads to the expected result; and

11 "wholesale" means sale to a person who purchases for the purpose of selling again and includes sale to a hospital or dispensary, or to medical, educational or research institute.

CHAPTER II

MANUFACTURE OF DRUGS FOR SALE

(4) Types of licences to manufacture drugs: Licences to manufacture drugs shall be of the following types, namely :--
(i) licence to manufacture by way of basic manufacture.

(ii) licence to manufacture by way of semi-basic manufacture;
(iii) licence to manufacture by way of formulation;

(iv) licence to manufacture by way of repacking; and

(v) licence to manufacture for experimental purposes.

(5) Manufacture on more than one set of premises: If drugs are manufactured on more than one set of premises, a separate application shall be made and a separate licence shall be issued in respect of each such set of premises.
(6) Application for licence to manufacture drugs and fee therefor: (1) An application for the grant or renewal of a licence referred to in clauses (i) to (iv) of rule 3 shall be made in Form 1 or l-A to the Central Licensing Board addressed to its Secretary.

12 An application under sub-rule (1) shall be accompanied by the proper fee as specified in Schedule F.

Proviso: Added vide S.R.O. 536(1)/93 dated 23rd June 1993. Omitted vide S.R.O. 2 77 (1)/96 dated 2 lst April 1996.

(d) If the application for renewal of the licence is made after the expiry of the period of the validity of the licence, it shall be treated as a fresh application for the grant of a licence.
(e) A fee of rupees one hundred shall be paid for a duplicate copy of the licence if the original is defaced, damaged or lost. Such copy of the licence shall bear the words "DUPLICATE COPY".
(f) Any fee deposited under sub-rule (2) Shall in no case be refunded.
(e) Duration of a licence to manufacture drugs: A licence issued under this Chapter shall, unless earlier suspended or cancelled, be inforce for a period of five years from the date of issue and may thereafter be renewed for periods of five years at a time:

Provided that an application for renewal shall not be entertained unless it has been made within sixty days after the expiry of the licence and when an application has been made as aforesaid the licence shall subject to the orders passed on the application for renewal continue in force for the next period of two years.

Provided further that duration of a licence issued under rule 21 shall be two years unless earlier suspended or cancelled.

14 Certificate of licence to manufacture drugs: A licence to manufacture by way of basic manufacture, semi-basic manufacture, formulation or repacking, as the case may be, shall be issued in Form 2.

8. Central Licensing Board: (1) The Central Licensing Board shall consist of the following members, namely :--

(f) the Director-General Health, Government of Pakistan, who shall be its ex-officio Chairman;

(g) the Director, Health Services of, each Provincial Government;
(h) two pharmacologists, to be nominated by the Federal Government.

(i) one pharmacist, to be nominated by the Federal Government;
(j) one medical specialist from the Army Medical Corps. to be nominated by the Federal Government.

(k) one pharmaceutical chemist or expert in quality control, to be nominated by the Federal Government;

(l) the Drugs Controller, Ministry of Health, Government of Pakistan who shall be its ex-officio Secretary;

(m) one representative, not below the status of an officer of BPS- 19 [.....], of each of the Ministries of Commerce Industries & Justice to be nominated by the Federal Government; and
(n) one representative of the Central Board of Revenue, not below the status of an officer of B - 20, to be nominated by the Federal Government;

(o) Cost Accountant of the Ministry of Health;

(p) One physician, to be nominated by the Federal Government;

18.One Surgeon, to be nominated by the Federal Government. or an officer of the Provincial Health Department not below the status of Additional Secretary, to be nominated by the Secretary, Health Department of that Province. and

17 one expert in veterinary medicine to be nominated by the Federal Government.

2 No person who is a member of the Appellate Board shall be nominated to the Central Licensing Board.

3 The members of the Central licensing Board, other than its ex officio members, shall hold office for three years and shall be eligible for renomination.

4 The Central Licensing Board may co-opt any other person who is expert in the pharmaceutical or medical profession for advice on any particular matter under consideration.

5 The meetings of the Central Licensing Board may be held at such time as the Board may deem fit and, on the request of any of its members, the Chairman may at any time call a meeting if there is any important matter for its consideration.

6 In the absence of the Chairman, the Board may elect one of its members to preside over a meeting.

(6-A) The quorum to constitute a meeting of the Board shall be one third of its total membership.

21. The Central Licensing Board may authorise the Chairman to any of its members to perform any specific function of the Board for a specified period.
22. The Central Licensing Board shall follow such policy directing as the Federal Government may issue from time to time.
23. No act or proceeding of the Central Licensing Board shall be invalid merely on the ground of the existence of any vacancy in, or any defect in the constitution of the Board.
24. The chairman and the Secretary of the Central Licensing Board shall, after the Board has approved the issuance of a licence sign the licence.
25. Subject to rule 14, the Central Licensing Board may appoint a licensing authority or authorities for such purpose as it may deem fit.
26. Powers of the Central Licensing Board: (1) The members of the Central Licensing Board shall exercise all the powers of an Inspector without restriction as to area, and shall have the powers of a Provincial Inspector in relation to Section 30.

(6) In the exercise of their powers the members of the Central Licensing Board shall follow the procedure prescribed for the Federal Inspector -

Provided that member nominated by a Provincial Government may follow the procedure as laid down for a Provincial Inspector.

19 Procedure of Central Licensing Board: (1) The Central Licensing Board may, before issuing a licence, cause the premises in which the manufacture is proposed to be conducted to be inspected by itself or by its sub-committee or by a panel of Inspector or experts appointed by it for the purpose, which may examine all portions of the premises and the plant and appliances, inspect the process of manufacture intended to be employed and the means to be employed for standarizing, if necessary, and analysing substances to be manufactured and enquire into the professional qualifications of the technical staff employed.

(7) Where inspection under sub-rule (1) is carried out by a sub-commmittee or panel of experts of Inspectors appointed under the said sub-rule it shall forward to the Central Licensing Board a detailed report of the result of the inspection.

(8) If the Central Licensing Board, after' such further enquiry, if any, as it may consider necessary, is satisfied that the requirements of the rules have been complied with, it may issue a licence in Form 2.

(9) If the Central Licensing Board is not so satisfied, it shall reject the application and shall inform the applicant of the reasons for such rejection and of the conditions which must be satisfied before a licence may be issued.

(10) No application shall be entertained within three months of the rejection of an application under sub-rule (4).

(11) If after the expiry of three months but within six months of the rejection of an application under sub-rule (4), the applicant informs the Central Licensing Board that the requirements of the rules have been fulfilled, the Board may if after causing a further inspection to be made, is satisfied that the conditions for the grant of a licence have been complied with, issue a licence and no further fee shall be required to be deposited for such an application.

(12) In case an application for licence to manufacture is made after the expiry of six months from the date of rejection of an application under sub-rule (1), such application shall be treated as a fresh application and full fee shall have to be deposited.

26. Special provisions regarding grant of a licence: (1) Where a manufacturer intends to manufacture a drug a part of the process of which is of specialised nature and would be uneconomical for him to conduct it, the Central Licensing Board may permit such process to be undertaken at another licensed premises specialised for this purpose, subject to such conditions, if any, as may be specified in this behalf.

20 If a person is conducting a part of the process of the manufacture on behalf of another manufacturer in accordance with the permission granted under sub-rule (1), and he is not responsible for the quality of the final product, the Central Licensing Board may not require him to establish an independent quality control laboratory for such products.

21 If a person possesses, or applies for, more than one type of licences to manufacture drugs in the same premises, he may establish one Quality Control Department for the purpose of both the licences.

2 Cancellation or suspension of licences: (1) If licensee does not comply with any of the conditions of a licence or violates any of the provisions of the Ordinance or the rules, or fails to deposit the requisite amount of the Central Research Fund due from him, the Central Licensing Board may, by an order in writing stating the reasons thereof, cancel a licence or suspend it for such period as it thinks fit, either wholly or in respect of some of the drugs to which it relates.

(7) The Central Licensing Board shall, before cancelling or suspending a licence under sub-rule provide an opportunity of being heard to the licensee.

27. When a licence is cancelled or suspended, an entry to that effect shall be recorded on the licence.

28. A licensee whose licence has been cancelled or suspended may appeal to the Appellate Board within sixty days of the date of receipt of the decision of the Central Licensing Board by the licensee and until the Appellate Board has given its order, the licence shall remain cancelled or suspended, as the case may be.

29. Renewal of a licence: On application being made for renewal, the Central Licensing Board may cause an inspection to be made, and if satisfied that the conditions of the licence and the rules are and will continue to be observed, shall issue a certificate of renewal or otherwise reject the application and inform the licencee accordingly.

30. Licensing authority: For the purpose of Section 18 of the Ordinance the Secretary to the Government of Province in the Health Department shall be the licensing authority for that Province.

31. Conditions for grant or renewal of a licence to manufacture drugs by way of basic or semi-basic manufacture: (1) Before a licence to manufacture by way of basic or semi-basic manufacture is granted or rehewed, the Central Licensing Board shall satisfy itself that the following conditions are complied with by the applicant, namely :--

22 The applicant shall provide premises which shall be suitable for intended use, in size and construction and shall be located in an area free from offensive and obnoxious odours and other possible sources of contamination.

23 The applicant shall provide adequate space, plant and equipment for the manufacturing operations;

24 The manufacture shall be conducted under the active directions and personal supervision of competent technical staff consisting of. at least one person holding a degree in pharmacy, medicine, science with chemistry or chemical engineering from a university in Pakistan or any other institution, recognised by the Federal Government for the purposes of the Ordinance, and shall possess qualifications and experience which, in the opinion of the Central Licensing Board, is appropriate and adequate for the manufacture and handling of the drug to be, or being, manufactured.

2 The applicant shall establish an independent Quality Control Department and maintain separate staff, premises and adequate laboratory equipment for carrying out tests of the strength, potency, quality and purity of the substances being or to be used in the manufacture.

3 The Quality Control Department shall be independent of the manufacturing units and its incharge shall be a whole -time employee of the manufacturer and shall possess a degree in pharmacy, or a degree in science with chemistry, or a degree in medicine, microbiology, pharmacology, or bacteriology from a university in Pakistan or any other institution recognised by the Federal Government for the purposes of Ordinance, as the Central Licensing Board may deem fit for any particular unit; and shall be independent of the incharge of the manufacture (Production Units).

4 the applicant shall ensure that--

30. the manufacturing premises shall be maintained properly and shall, as far as possible, be orderly , clean and free from accumulated waste and vermin;

31. unhygienic practices eating and smoking shall not take place in any production or quality control area;

31. sufficiently clean, appropriately ventilated toilet facilities, including facilities for washing and room for changing clothes, shall be available for the use of manufacturing personnel where required;

23 hygienic garments shall be worn by all staff in processing and packaging areas;
24 high standard of personnel hygiene shall be observed by all persons concerned with production processes, and

25 no person known to be suffering from communicable disease or to be a carrier of such a disease and no person with. open lesions or skin infection shall be engaged in production areas.

2 The applicant shall provide--
(4) adequate facilities for first aid;

2 medical inspection of workers at the time of employment and periodical check up thereafter at least once a year;

33. facilities for vaccination and inoculation against the enteric or any other epidemic group of diseases; and

(iv) adequate precautions for safe -guarding the health of the workers, including measures to avoid industrial accidents or diseases.

Provided that where a person possess or applies for a licence to manufacture by way of basic and he also intends to conduct semi-basic manufacture of drugs, he may conduct such manufacture under the same license, subject to the approval of, and under such conditions as, the Central Licensing Board may specify, and

24 Conditions for the grant or renewal of licence to manufacture drugs by way of formulation: Before a licence to manufacture drugs by way of formulation is granted or renewed, the Central Licensing Board shall satisfy itself that the following conditions are being complied with by the applicant namely :--

7. The factory premises shall comply with the conditions specified in Schedule B.

8. The applicant shall provide adequate space, plant and equipment for the manufacturing operations, the minimum space, plant and equipment for various operations are specified in Schedule B-1.

2 An applicant for registration of insecticides, pesticides and household disinfectants shall, in addition to the conditions specified in Schedule B and Schedule B-l, comply with the conditions specified in Schedule B-l, A.

35. The manufacture shall be conducted under the 'active directions and personal supervisions of competent technical staff conisting of at least one person who is a whole -time employee and who has--
36. a degree in Pharmacy from a university in Pakistan or any other institution recognised by the Federal Government for the purpose of the Ordinance and has at least twelve months of practical experience in the manufacture of drugs; or
37. a degree in science with chemistry or pharmaceutical chemistry as the principal subject who, for the time being is working as incharge of a licensed pharmaceutical manufacturing unit, has not less than ten years practical experience in the manufacture of drugs intended to be manufactured knowledge of pharmacy which, in the opinion of the Central Licensing Board is adequate for the purposes; or
38. any foreign qualification the quality and content of the training of which are comparable with those described in sub-clause (i) or sub-clause (ii) and is approved for the purposes, of this sub-rule by the Central Licensing Board: Provided that the Central Licensing Board may, in the case of manufacture of drugs included in Schedule C, permit the manufacture of such drugs under the active direction and personal supervision or a person holding a degree in medicine or veterinary sciences of a university in Pakistan or any o ther institution recognised by the Federal Government, with at least three years experience in the manufacture, testing and analysis of biological products which are intended to be produced:

Provided further that the Central Licensing Board, may, in the case of anufacture of disinfectant fluids, insecticides liquid paraffin, medicinal gases, non-chemical contraceptives, plaster of paris, surgical dressing or chemicals for the manufacture of which the knowledge of pharmacy or pharmaceutical chemistry is not essential, permit manufacture of the drug under the active direction and personal supervision of competent staff who, […..] has in the opinion

of the Central Licensing Board, adequate knowledge and experience in the manufacture of the drug (s) to be produced.

24 The applicant shall establish an independent Quality Control Department and maintain separate staff, premises and adequate laboratory equipment for carrying out tests of strength, quality and purity of the substances being or to be used in the manufacture.

Provided further that a person already approved by the Central Licensing Board as the production incharge of a pharmaceutical firm shall continue to be the technical supervisor of that firm for the purposes of this rule.

7. The Quality Control Department shall be independent of the manufacturing unit and its incharge shall be whole time employee of the manufacturer and shall possess a degree in pharmacy, or a degree in science with chemistry or a degree in medicine or pharmacology (for pharmacological testing) or a degree in microbiology (for microbiological testing) and has sufficient experience in testing of drugs:

Provided that in the case of drugs specified in Schedule C, the Central Licensing Board may allow the applicant to make arrangements with some other institution approved by the Central Licensing Board for such tests to be regularly carried out on his behalf by that institution.

37. Licence to manufacture drugs by way of repacking: (1) A licence to manufacture drugs by way of repacking is required for the repacking of such drugs, and under such conditions, as are specified in Schedule D.

2 Where a person possesses or applies for a licence to manufacture by way of formulation and he also intends to conduct repacking of drugs, he may conduct such repacking under the same licence subject to the approval of, and under such conditions as, the Central Licensing Board may specify.

39. Condition for the grant or renewal of a licence to manufacture drugs by way of repacking: Before a licence to manufacture drugs by way of repacking is granted or renewed, the Central Licensing Board shall satisfy itself that the following conditions are complied with by the applicant, namely :--

26 adequate space and equipment shall be provided;

27 repacking operation shall be carried out under hygienic conditions and under supervision of technical staff provided for in clause (c) of rule 16;

28 adequate arrangements shall be provided for carrying out the tests for strength potency, quality and purity of the drugs to be repacked.

(vii) Conditions of licence to manufacture, by way of basic manufacture, semi-basic manufacture formulation and repacking of drugs: (1) A licence to manufacture by way of basic, semi-basic manufacture, formulation or repacking of drugs shall be subject to the conditions stated herein, if any, and to the further condition that the licensee shall continue to maintain conditions on the basis of which he was granted a licence.

27 The licence shall be kept on the licenced premises and shall be p roduced at the request of any member of the Central Licensing Board or of Provincial Quality Control Board or an Inspector.

28 Any change in the expert staff or significant alteration in the licensed premises or equipment shall be immediately notified to the Central Licensing Board.

29 The licensee shall maintain in the inspection book provided by the Central Licensing Board at the time of the issuance of the licence on which a member of the said Board or of a Provincial Quality Control Board or an Inspector shall record proceedings of each of his visits, his impressions and the defect or irregularities noticed, if any, by him and such inspection book shall be signed by him as well as the licensee or his authorised agent.

30 If any defects or irregularities are recorded in the inspection book under sub-rule (4) the manufacturer shall take steps to remove such defects or irregularities.

31 A licensee who for any purpose is engaged in the culture or manipulation of pathogenic spore bearing micro -organisms shall provide, to the satisfaction of the Central Licensing Board, separate laboratories, utensils and apparatus required for the culture or manipulation of such .micro-organisms, and they shall not be used for the manufacture of any other substance.

32 The licensee shall comply with the provisions of the Ordinance and the rules and with such further requirements, if any, as may be specified in any rule subsequently made-in this behalf or any other condition that may be imposed at the time of grant of a licence in the special circumstances of each case.

33 The licensee shall allow any member of the Central Licensing Board or of a Provincial Quality Control Board or an Inspector to enter, with or without prior notice, any premises and to inspect the plant and the process of manufacture & the means employed in standardising and testing the drugs and to take samples for test and analysis.

34 The licensee shall allow any member of the Central Licensing "Board or of a Provincial Quality Control Board of an Inspector to inspect all registers and records maintained under these rules and to take samples of the manufactured drugs and shall supply to such member

or Inspector such information as he may require for the purpose of ascertaining whether the provisions of the Ordinance and the rules have been observed.

b The Licensee shall, on demand, furnish to the Central Licensing Board or the Provincial Quality Control Board or to such authority as the Central Licensing Board may direct, from every batch of a drug, or from such batch or batches of drugs as it may from time to time specify, a sample for examination and, if required, furnish full Protocols of the tests which have been applied.

c If the Central Licensing Board or a Provincial Quality Control Board so directs, the licensee shall not sell or offer for sale any batch of a drug in respect of which a sample is, or protocols are, furnished under clause (10) until a certificate authorising the sale of the batch of such drug has been issued to him by or on behalf of the Central Licensing Board or the Provincial Quality Control Board, as the case may be.

d The licensee shall on being informed by the Central Licensing Board or a Provincial Quality Control Board that any part of any batch of a drug has been found not to conform with the requirements of the Ordinance or the rules and on being directed so to do, withdraw the remainder of the batch of such drug from sale and, so far as may in the particular circumstances of the case be practicable, recall all issues already made from that batch and dispose it of in such manner as may be directed by the said Board.

e No drug manufactured under licence shall be sold unless the precautions necessary for preserving its properties have been observed throughout the period after manufacture.

(13-A) The licensee or his authorised agent shall issue a warranty in Form 2 -A For any drug sold by him for the purpose of re -sale or distribution.

f The Licensee shall , by the 30th June and the 31st December each year, Whichever is immediately after the annual financial closing of the company. contribute one per cent of his gross profit before deduction of income -tax towards the Central Research Fund to be maintained by the Federal Government and utilised by it in accordance with the Drugs (Research) Rules, 1978:

Provided that the Central Licensing Board may allow a portion of such contribution to be spent by the firm itself for research and development of new drugs or for establishing research laboratories when it is fully satisfied that such expenditure will be utilised for the said purpose effectively and properly.

Explanation: In this sub-rule, "profit" means gross profit before payment of income tax or other tax.

(14-A) The contributions made towards the Central 'Research Fund under sub-rule (14) shall be kept in such bank as the Federal Government may specify and shall be utilised in accordance with the Drugs (Research) Rules, 1978.

(c) The licensee shall, on or before the 31st July each year, submit a duly Signed profit and loss statement as per "PROFORMA" given in FORM-1 of SCHEDULE-A alongwith an evidence of deposit of 1 per cent of profit towards the Central Research Fund;

(vi) Additional conditions of licence to manufacture drugs by way of formulation: A licence to manufacture drugs by way of formulation shall, in addition to the conditions laid down in rule 19, be subject to the following further conditions, namely :--

(iii) The licensee shall comply with the requirements and the conditions in respect of goods practices in the manufacture and quality control of drug; as specified in Schedule B-II.

(iv) The licensee shall record in Schedule B-Ill the particulars of manufacture of each batch of drugs manufactured by him and shall retain such records, in the case of a substance for which expiry date is fixed for a period of two years from the expiry of

such date and, in the case of other substances, for a period of five years from the date of manufacture.

b The licensee shall either in his own laboratory or, where so authorised u nder the proviso to clause (e) of rule 16, in any other laboratory approved by the Central Licensing Board, test each batch of the raw materials used by him for the manufacture of drugs and also each batch of the final drug, shall maintain records showing the particulars in respect of such tests as specified in Schedule B-III and shall retain such records, in the case of a substance for which expiry date is fixed for a period of two years from the expiry of such date and, in the case of other substances, for a period of five years from the date of manufacture.

20A. Contract Manufacture.-- Manufacture or analysis on contract is permissible on behalf of a licensee or of a pharmaceutical company whose products are registered in Pakistan for sale subject to the conditions laid down in Schedule G," as a special case and for genuine reasons as approved by the Registration Board.

SCHEDULE 'G'

1. Contract production and analysis

1.1 Contract of manufacture shall be undertaken only by a manufacturer who hold a valid d rug manufacturing license, and the contract acceptor shall/have adequate facilities, knowledge, experience and competent personnel to satisfactorily carry out the work ordered by the contract giver.

1.2 General.-- Contract production and analysis shall be correctly defined, agreed and controlled in order to avoid misunderstandings that could result in a drug or work or analysis of unsatisfactory quality. A written contract between the contract giver and the contract acceptor shall clearly establish the duties of each party had state the way in which the authorized person shall exercise his full responsibility in releasing each batch of product for sale or issuing the certificate of analysis and a copy of such a contract shall be supplied to the Central Licensing Board also.

1.3 All arrangements for contract manufacture and analysis, including any proposed changes in technical or other arrangements, shall be in accordance with the registration of the drug concerned.

1.4 There shall be a written contract covering the manufacture and or analysis arranged, under contract and any technical arrangements made in connection with it.

1.5 The contract shall permit the contract giver to audit the facilities of the contract acceptor.

1.6 In the case of contract analysis, the final approval for release must be given by the authorized person(s).

2. Contract Giver

2.1 The contract giver shall be responsible for assessing the competence of the contract acceptor in successfully carrying out the work or tests required and for ensuring by means of the contract that the principles of good manufacturing practices are followed.

2.2 The contract giver shall provide the contract acceptor with all the information necessary to carry out the contracted operations correctly in accordance w ith the registration and any other legal requirements and the contract giver shall ensure that the contract acceptor is fully aware of any problem associated with the product, work, or tests that might pose a hazard to premises, equipment , personnel, other materials or other products.

2.3 The contract giver shall ensure that all processed products and materials delivered by the contract acceptor to comply with their specifications or that the product has been released by the authorised person(s).

3. Contract acceptor

3.1 The contract acceptor shall not pass to a third party any of the work entrusted to him or her under the contract without the written consent of the contract giver and prior evaluation and approval by the arrangements of the Central Licensing Board, and arrangements made between the contract acceptor and any third party shall ensure that the manufacturing and analytical information is made available in the same way as between the original contract giver and contract acceptor.

3.2 The contract acceptor shall refrain from any activity that may adversely affect the quality of the product manufactured and or analyzed for the contract giver.

4. The contract

4.1 A contract shall be drawn up between the contract giver and contract acceptor that specifies their respective responsibilities relating to the manufacture and control of the product, and technical aspects of the contract shall be drawn up by competent persons suitably knowledgeable in pharmaceutical technology, analysis, and good manufacturing practices. All arrangements for production and analysis must be in accordance with the registration and agreed by both parties.

4.2 The contract shall specify the way in which the authorized person releasing the batch for sale ensures that each batch has been manufactured in, and checked for, compliance with the requirements of the marketing authorization.

4.3 The contract shall be describe clearly who is responsible for purchasing, testing and releasing materials and for undertaking production and quality controls, including in-process controls, and who has responsibility for sampling and analysis, and in the case of contract analysis, the contract shall state whether or not the contract acceptor shall take samples at the premises of the manufacturer.

4.4 Manufacturing, analytical and distribution records and reference samples shall be kept by, or be available to, the contract giver, and any records relevant to assessing the quality of a product in the event of complaints or a suspected defect shall be accessible and specified in the defect or recall procedures of the contract giver.

4.5 The contract shall describe the handling of starting materials, intermediate and bulk products and finished products if they are rejected and it shall also describe the processing of information if the contract analysis shows that the tested product must be rejected.

(d) Licence to manufacture drugs for experimental purposes: (1) If a person intending to manufacture a drug for experimental purposes does not hold a licence to

manufacture drugs, he shall before commencing such manufacture, apply in Form 3 for the grant or renewal of a licence to the Central Licensing Board addressed to its Secretary.

(vi) An application under sub-rule (1) shall be countersigned by the head of the institution in which,. or the director or manager of the firm or company by which, the drug will be manufactured.

(vii) The licence for the manufacture of drugs for experimental purposes shall be in Form 4.

(vii) Conditions of licence to manufacture drugs for experimental proposes: A licence issuing under rule 21 shall be subject to the following conditions, namely :--

(iv) That licensee shall use the drugs manufactured under the licence exclusively for experimental purposes and shall carry on the manufacture and experimental work at the place specified in the licence.

(v) The licensee shall allow a member of the Central Licensing Board or of a Provincial Quality Control Board or an Inspector to enter, with or without notice, the premises where the drugs are manufactured and to satisfy himself that the manufacture is being conducted for experimental purposes.

28 The licensee shall comply with such further requirements, if any, as may be specified under any rule subsequently made.

42. Labeling of drugs manufactured for experimental purposes: (l) Any d -rug manufactured for experimental purposes shall be kept in containers bearing labels indicating the purpose for which it has been manufactured.

28 If any drug manufactured for experimental purposes is supplied by the manufacturer to any other person, the container shall bear a label on which shall be stated the name and address of the manufacturer, the accepted scientific name of the drug, if known, or, if not known, a reference which will enable the drug to be identified and the purpose for which it has been manufactured.

CHAPTER 3

REGISTRATION OF DRUGS

45. Registration Board: (1) The Registration Board shall consist of such members, including the

Chairman and the Secretary, and its members -shall hold office for s uch term, as is prescribed for the Central Licensing Board set up under rule 8.

46. The Registration Board may refer any case for detailed .examination to the committee of experts on the Drugs Evaluation constituted under Section 10 of the Act.

47. The Registration Board may appoint a sub-committee consisting of at least one Clinical Professor, one pharmacologist and one pharmacist to make a detailed examination of each case and to submit a report for the consideration of the Board.

48. The Registration Board may appoint a panel of experts or inspectors to inspect on behalf of the Board the premises of a manufacturer of drugs and to submit its report to the Board.

49. The Chairman and the Secretary of the Registration Board shall, after the Board has approved the registration of a drug, sign the certificate of registration.

50. For the manner and conduct of the meetings of the Registration Board, the provisions of sub-rules (3), (4), (5), (6), (7), (8), and (9) of rule 8 shall mutatis mutandis apply.

2 Powers of Registration Board: The members of the Registration Board shall exercise all the powers of Inspector without restriction as the area, and shall have the powers of a Provincial Inspector in relation to Section 30.

3 Application for registration of d rugs and fees thereof: (1) An application for registration of a drug shall be made in Form 5 or 5 -A in duplicate to the Registration Board addressed to its Secretary, and separate application shall be made for each drug.

2 The applicant shall furnish such further information and material as may be required by the Registration Board for the proper evaluation of the drug.

47. An application under sub-rule (1) shall be accompanied by fee or--

(a) rupees one thousand for the registration of new drug;

(b) rupees five hundred for the registration of any other drug; and

(c) rupees two hundred and fifty for the renewal of the registration of a new or any other drug:

Provided that the application for the renewal of registration is made before the expiry of the validity of the certificate of registration.

(3-A) Application for renewal of registration of a drug shall be made in Form 5 -B.

(3-B) Any application under sub-rule (1) or sub-rule (3) shall be accompanied by the proper

fee specified in Schedule F.

30 If the application for renewal of registration is made after the expiry of the period of the validity of the certificate or registration, it shall be treated as a fresh application for the registration of drug.

31 A fee of rupees fifty shall be paid for a duplicate copy of the certificate of registration if the original is defaced, damaged or lost, and such copy of the certificate shall bear the words "Duplicate Copy".

32 Any fee deposited under sub-rule (3)shall in no case be refunded.

(f) Duration of certificate of registration: A certificate of registration under this chapter, shall, unless earlier suspended or cancelled, be. in force for a period of five years from the date of Registration of the drug and may thereafter be renewed for periods not exceeding 5 years at a time.

Provided that an application for the renewal of registration shall not be entertained unless it has been made within sixty days after the expiry of the registration and when an application has been made as aforesaid the registration shall subject to the orders passed on the application for the renewal continue in force for the next period of five years :

Provided further that, if in the opinion of the Registration Board it is necessary so to do in the Public interest, it may provisionally register a [....] drug for period of two years.

31 Certificate of registration: A certificate of registration of drug shall be issued in Form 6.

32 Procedure for registration: (1) The Registration Board may, if it considers necessary, cause the application for registration and the information and material supplied to it under rule 31 to be evaluated by a Committee on Drugs Evaluation consisting of experts related to the aspect of the drug to be evaluated and obtain its report.

2 The Registration (2) The Registration Board may, before issuing a registration], cause the premises in which the manufacture is proposed to be conducted to be inspected by itself or by its sub-committee or by a panel of Inspectors or experts appointed by it for the purpose, which may examine all portions of the premises and the plant and appliances, inspect the process of manufacture intended to be employed and the means to be employed for standardising, if necessary, and testing the substances to be manufactured and enquire into the professional qualifications of the technical staff employed.

3 Where inspection under sub-rule (2) is carried out by a Sub-Committee or panel of experts or Inspectors appointed under the said sub-rule, it shall forward to the Registration Board a detailed report of ;he result of the inspection.

4 If the Registration Board, after such further enquiry, if any, as it may consider necessary, is satisfied of its safety, efficacy, quality and economical value or where the public interest so

requires, it may register the drug and issue a certificate of registration in Form 6, subject to such specific conditions as it may specify.'

48. The Registration Board may, while registering a drug under sub-rule (4), approve the details as supplied by the applicant or approve them with amendments as it may deem fit in respect of the following particulars, namely :--

13 the name under which the drug may be sold;

14 the labelling;

15 the statement of all the representations to be made for the promotion of the drug in respect of--

2 the claims to be made for the drug;

49. the route of administration;

(g) the dosage;

(iv) the contra-indications, the side effects and precautions if any; and

52. Omitted by S.R.O. 551(1)//93, dated 3. 7. 1993.

(5-A) Where the Registration Board registers a new drug, it may recommend to the Federal Government for fixation of maximum price of such drug.

32 The Registration Board shall, before registering a new drug for which the research work has been conducted in other countries and its efficacy, safety and quality has been established therein, require the investigation on such pharmaceutical, pharmacological and other aspects, to be conducted and clinical trials to be made as are necessary to establish its quality and, where applicable, the biological, availability, and its safety and efficacy to be established under the local conditions:

Provided that under special circumstances to be recorded in writing, the Registration Board may register a drug and require such investigations and clinical trials to be conducted after its registration.

55. A new drug, where new method of manufacture is contemplated or a change is proposed in source, standard or specification of the active ingredient or the finished product, may not require full investigations and clinical trials except in so far as they are necessary for the purpose of establishing bio -equivalence, absorption, acceptability or other such features.

56. Where it is necessary in the public interest so to do, the Registration Board may register a drug on its own motion without having received any application for registration.

57. If the Registration Board is not satisfied as to the safety, efficacy, quality or economic value of a drug, or where the public interest so requires it may, [.]..., reject the application for registration and inform the applicant of the reasons for such rejection in writing.

58. Rejection of an application for the registration of a drug shall not debar an applicant from submitting a fresh application under rule 26.

56. Conditions or registration of drug: (1) The relevant provisions of the Ordinance and the rules in respect of the registered drug, shall be complied with.

33 The import, manufacture and sale of drugs shall be in accordance with the information contained in the applications in respect of those drugs or in any supplementary information or, where such information was amended by the Registration Board, in accordance with such amended information on the basis of which such drugs were registered:

Provided that deviations from any such information may be made only after obtaining prior approval of the Registration Board.

60. he indications, contra-indication, side effects, the dosage and cautions, if any, as have been approved for the purpose of registration of a drug shall be clearly specified in the labelling and promotion.

61. Every drug shall be produced in sufficient quantity so as to ensure its regular and adequate supply in the market.

62. The manufacture of any drug shall not, without the prior approval of the Registration Board, be discontinued for period which may result in its shortage:

Provided that in the circumstances beyond the control of a manufacturer,, of a drug which may lead to reduction in the production of that drug, the circumstances may be intimated to the Registration Board.

33 A record of quarterly production and disposal of a drug shall be maintained and supplied to the Chairman of the Registration Board in Form 7 in the months of January, April, July and October each year.

34 In case of an imported drug, the indenter or any other approved representative in Pakistan of the foreign firm shall ensure regular and adequate supply of tee drug in Pakistan.

(7-A) The indenter, importer or manufacturer's authorised agent shall issue a warranty in Form 2-A for any drug indented or sold by him for the purpose of re -sale or distribution; and

(d) In respect of new drug, records, including adequately organised and indexed files, shall be maintained containing full information regarding--

36 animal or clinical investigations and tests conducted by the manufacturer or reported to him by any person concerning

that drug;

37 reports from the scientific literature or the bibliography therefrom that are available to him concerning that drug;

38 experiences, investigations, studies and tests involving the chemical or physical properties or any other properties of that drug;

39 any substitution of another substance for that drug or any mixing of another substance with that drug;

40 any error in the labelling of that drug;

41 any bacteriological or any significant chemical or physical or other change or deterioration in any batch of that drug;

42 any failure of one or more distributed batches of that drug to meet the required specifications;

43 any unexpected side effects, injury, toxicity or sensitivity reaction associated with the clinical uses, studies, investigations and tests respecting that drug; and

44 any unusual failure of that drug to product it expected pharmacological activity.

(9) The following information shall be supplied to the Registration Board --

ii on request, report in duplicate of all records respecting the information contemplated by paragraphs (d), (e), and (f) of

sub-rule (8); and

iii immediately upon receipt by him, reports in duplicate of all records respecting the information contemplated by paragraphs (d), (e) and (f) of sub-rule (8); and

iv as soon as possible and in any event within fifteen working days of their receipt by him, reports in duplicate of all records respecting the information contemplated by paragraphs (g),

(vii) and (i) of sub-rule (8).

b If a drug or any of its ingredients, which is imported or manufactured by a company in Pakistan is also approved for registration and free sale by its subsidiary, sister concern, associate or parent company in the country where it was originally developed or in any of the countries namely, USA, European Union Countries, Canada, Japan, Australia, and--

(e) if that drug at any time, for safety reasons is withdrawn or banned or certain restrictions are imposed in any of the said countries, then it shall be the responsibility of the manufacturer in Pakistan or as the case may be, the indentor, to immediately withdraw the drug from the market in Pakistan or, as the case may be to impose similar restriction and to inform the registration Board within fourteen days of such an information having come to his knowledge and having taken the necessary action. The Registration Board after getting the said intimation shall take similar action for the same drug available from other sources within the shortest possible time;

(f) if a clinical information for a drug is approved by the Drug Regulatory Authority in any of the said countries, the same clinical information shall be considered as approved for drug registration in Pakistan unless modified by the Registration Board on the basis of scientific data available to it, and such clinical information may include indication, contra-indications, side effects, precautions, dosage, etc;

(g) if any adverse drug reaction not otherwise included in the application for registration, is registration, is registered in any of the said countries, it shall be the responsibility of the concerned manufacturer or in case of imported drugs the indentor or manufacturer's agent in Pakistan, to be aware of such adverse action and to report to the Registration Board within thirty days of becoming so aware.

(iv) The manufacturer or as the case may be, the indentor shall follow the ethical criteria for medical drug promotion as given in Schedule G.
(v) The manufacturer or, as the case may be, the indentor shall supply the information in relation to safety, efficacy, production, quality, or availability of the drugs as and when required by the Registration Board with a view to ensure safety, efficacy or quality of the drug, and

CHAPTER IV

ADVERTISING OF DRUGS, Etc.

2 Conditions for Advertising: (1) The Federal Government may, after seeking advice of the Committee on Advertising, allow the advertisement of a drug, or any substance or a remedy as specified in Schedule D-1 or a treatment or offer of a treatment for any disease. approve the contents of such advertisement and specify conditions subject to which such advertisement shall be made:
Provided that the Federal Government may, if in its opinion the public interest so required, withdraw the approval granted to any advertisement or modify or alter any condition subject to which the advertisement was approved.

(1-A) An application for advertisement of any drug, substance, remedy, treatment or offer of treatment for any disease shall be made it Form-8, addressed to the Secretary of the Commissioner on Advertising and there shall be made a separate application for each advertisement.

(l-B) An application under sub-rule (l-A) shall be accompanied by the proper fee specified in Schedule F : and

(1-C) The approval of the advertisement, granted under sub-rule (1), shall be valid for a period of two years only.

61. A drug or any substance referred to in clause (ii) of Sec. 24 may be advertised to the medical, pharmaceutical and allied professions, without referring to the Federal Government, through medical representatives or through professional journals and publication which are meant for circulation exclusively amongst the members of the medical, pharmaceutical and allied professions •

Provided that:

(i)one copy of each issue of such journal or publication is sent to the Drug Administration of the Health Division; and

(e) the Federal Government may, after giving an opportunity of being heard, prohibit the publication of any advertisement in any such journal as it is found to violate any of the conditions specified under sub-rule (1).

(g) Advertisements under sub-rule (2) shall be subjected to the following conditions, namely :--

(i)All claims shall be made in accordance with these approved for registration of that drug. (ii) Where the usual information on indications and dosage is provided, that advertisement material shall contain information on contra-indications, side effects and other necessary precautions as may be applicable.

(h) A drug or any substance referred to in clause (ii) of Section 24, may be advertised through Press without reference to the Federal Government if it is merely intended to inform the public of the availability or the price of such drug or any substance referred to in clause (ii) of Section 24 subject to the condition that the Federal Government may prohibit such advertisement if, in its opinion, the public interest so requires.

(i) A drug or any substance referred to in clause (ii) of Section 24, may be advertised to the medical, pharmaceutical and allied professions through a documentary film.

(j) No advertisement under this rule shall contain any direct or indirect comparison in any way with any other drug or substance or remedy for any disease for the purpose of attracting customers or with a view to discredit other such product.

(k) Advertisement material shall be presented with courtesy and good taste and words and phrases implying urgency, uniqueness or such expressions which are absolute in character, such as "the most potent", "the most rapid", "the most efficacious", or which make exaggerated claims or to general claims, such as "effective in all cases" or "effective against all complaints" or superlatives shall be avoided.

(l) Advertisement of a drug or any substance referred to in clause (ii) of Section 24 shall include such information or any risks and other precautions as may be necessary for the protection of public health, and in the case of drug also its maximum retail price fixed under Section 12.

(m) No drug or any other substance shall be advertised in a manner which encourages self-medication or use to the extent that it endangers health.

(n) No drug or any remedy, treatment or after treatment of any disease specified in Schedule 'E' shall be advertised except as provided in sub-rule (2).

(o) Reminder publications for the medical, pharmaceutical and allied professions shall include the name of the drug and its exact composition, the price, the name and address of the manufacturer and a statement to the effect that "Full information is available on request".

(4) Sampling of drugs: Samples of drugs may be provided to the physicians or dentists or Pharmacists or Veterinarians or a medical institution in a reasonable quantity and in reduced packings marked with the words "Physicians Sample Not for Sale".

(5) Expenditure on advertisement: No person shall spend more than five per cent of his turnover on advertisement, sampling and other promotional activities in respect of drugs,

Explanation: The expenditure on pay and allowances of the field force connected with the promotional activities shall not be included in expenditure for the purpose of this rule.

37 Substances required to be prescribed under Section 24: Any substance or a mixture of substances offered for sale which is injurious, or likely to become hazardous, to the health of a person shall be deemed to be a substance for the purpose of Section 24 of the Ordinance.

38 Retailer's discount: The retailers discount shall be 15% of the maximum retail price.

SCHEDULE A

[See rule 2 (e)]

Form 1

[See rule 5 (/)]

APPLICATION FORM GRANT OF A LICENCE TO MANUFACTURE BY WAY OF FORMULATION/BASIC MANUFACTURE/SEMI-BASIC MANUFACTURE/REPACKING

I/We .....of .....hereby apply for the grant of a licence to manufacture by way of.....on premises situated at .....

2 The drug(s) or class(es) of drugs intended to be manufactured :-

(1) Class(es) of drugs.

(2) Dosage form(s) of drugs.

(3) Name of the drug(s).

3 I enclose :-

64. Particulars regarding the legal status of the applicant (i.e. in case of proprietorship the names) of proprietors and their address (es), in the case of firm the name and names and addresses of its partners and in the case of company the name and address of the company and its directors).

65. Details of the premises including layout plan of the factory.

66. Details of the section-wise equipment and machinery for manufacture and quality control.

67. Names and qualifications of the Production Incharge and Quality Control Incharge for supervising manufacturing processes and Quality Control Department, and other technical staff working in these departments.

4. The premises and plan will be ready for inspectionon or are ready for inspection.

Dated..... Signed……

Place..... Name, designation and address .....

PROFORMA

DETAILS OF THE FIRM

Name of the Company .....Type of ownership (Partnership, Proprietorship, Public

limited, Private limited, etc.)

Name(s) of Proprietor(s)/Director(s)/Partner(s).

Date of Establishment.

Initial investment (and details of equity shares).

Present investment (and details of equity shares).

Profit and loss statement as per audited accounts for the last five years :

Year

Investment Turnover Profit before tax Percentage 1% before tax for Central Research Fund percentage of Profit

Calculated Paid investment Turnover

Note: Copies of balance sheets to be enclosed with the application for renewal only"; and

2 in. Schedule B, in paragraph (2), in clause (k), for the semi colon and word"; and" a colon shall be substituted and thereafter the following proviso shall be inserted, namely:

Provided that the conditions of location may be relaxed by the Board in suitable cases for grant or renewal or a licence subject to such conditions as it may deem fit, if the surroundings and the premises, in the opinion of the Board, are satisfactory for the intended manufacture.

FORM 1-A

[See rule (5(I)]

APPLICATION FORM FOR RENEWAL OF A LICENCE TO MANUFACTURE DURGS BY WAY OF FORMULATION/BASIC MANUFACTURE/SEMI-BA SIC MANUFACTURE/REPACKING

I/We ..... of ..... hereby apply for the renewal of a licence to

manufacture by way of on premises situated at .....

65. The drug(s) or class(es)of drugs intended to be continued to be manufactured:-

(i) Class(es) of drugs.

(ii) Dossage form(s) of drugs.

(iii) Name of the drug(s) registered/approved.

66. There have been/have not been any change in respect of

(3)Name of the proprietor/directors/partner(s)

(4) Details of the premises including layout plan of the factory.
(5) Details of the section-wise equipment and machinery for manufacture and quality control.

(6) Names and qualifications of the Production Incharge and Quality Control Incharge for supervision of manufacturing processes and Quality Control Departments, and other technical staff working in these departments

4. Statement of the Central Research Fund.

Attested copies of the last two income tax assessment orders of the Income Tax Department attached.

Following statement, as per audited accounts/based on Income Tax Return for the last five years:-

Year Investment Turn-over

CRF due C R F paid as per Col. 41 2 3 4 5

Date Signed…….

Place Name, designation and address of the signatory .....

Note:-Strike off which is not applicable

FORM 2

[See rule 7] GOVERNMENT OF PAKISTAN

Licence to Manufacture

is/are hereby licensed to manufacture by way of Basic Manufacture/Semi Basic manufacture/Formulation/Repacking at the following premises:-

2. This licence permits the manufacture of

67. This licence shall, in addition to the conditions specified in the rules made under the Drugs Ordinance/Act, 1976, be subject to the following conditions namely:-

68. The licence will be in force for a period of five years from the date of issue unless earlier suspended or cancelled.

69. The licence authorises the sale by way of wholesale dealing and storage for sale by the licensee of the products manufactured under this licence, subject to the conditions applicable to licences for sale.

70. Name of the approved expert staff.

.....

....

.....

Date of issue .....

Secretary, Central Licensing Board. (Seal) Chairman, Central Licensing Board.

FORM 2A

(See rules 19 and 30)

Warranty under Section 23(I)(i) of the Drugs Act, 1976

I.....being a person resident in Pakistan, carrying on business at (full address) ..... under the name of.....(and being an importer/indenter/authorised agent of .....), do hereby give this warranty that the drugs here-under described as

sold/indented by me/specified and contained in the bill of sale, invoice, bill of lading or other

document describing the goods referred to herein do not contravene in any way the provisions

of section 23 of the Drugs Act, 19.76.

Dated (Signed)

38 Name(s)• of the drug(s):

(i)

(ii) Batch number(s)

39 Description of bill of sale, invoice, bill of lading or other document (if any).
Signed .....

FORM 3

[See rule 21(I)]

APPLICATION FOR LICENCE TO MANUFACTURE DRUG(S) FOR EXPERIMENTAL PURPOSES.

I/We ..... of ..... hereby apply for a licence to manufacture drug(s) specified below for experimental purposes at ..... and I/We undertake to comply with the

conditions applicable to the licence under rule 22 of the Drugs (Licensing, Registering and Advertising) Rules, 1976.

2 Name and quantity of drug(s) to be manufactured for the said purposes:.
Signature.....
Name .....

Address .....

Countersigned by .....

FORM 4

[See rule 21(3)]

LICENCE TO MANUFACTURE DRUG(S)

FOR EXPERIMENTAL PURPOSES

Mr./Messrs ..... of ..... is/are hereby licensed to manufacture the drug(s)

specified below for experimental purposes at ..... :. or at such other place(s)

at the. Central Licensing Board may from time to time permit.

71. The licence is subject to the conditions prescribed in rule 22 of the Drugs (Licensing, Registering and Advertising) Rules, 1976, and such other conditions as n3ay be subsequently prescribed or Specified by the Central Licensing Board in this behalf.

72. This licence shall unless previously suspended or cancelled be in force for a period of two years from the date specified below:-

Name of drugs with quantity to be manufactured.

Date:.....

Place:..... Licensing Authority.

FORM 5

[See rule 26(I)]

APPLICATION FORM FOR REGISTRATION OF A DRUG FOR LOCAL MANUFACTURE
I/we.....of .....hereby apply for registration of the drug namely

.....details of which are enclosed.

Date .....

Place .....

ENCLOSURE OF THE APPLICATION FOR REGISTRATION OF A DRUG
1. Name and address of the manufacturer •

2, Name of drug •

39 Generic/international non-proprietary name:

40 Proprietory name, if any:
3 Name under which drug is proposed to be sold

8. Dosage from of the drug:
9. Composition of the drug, stating quantity of each active and non-active ingredient(s) per unit or as a percent age of total formulation :
10. Proposed dosage :

40 for adults.

41 children by age group.
42 infant

43 special groups.

17. Main Pharmacological group to which the drug belongs:
18. Pharmacological and clinical data :

18. recommended clinical use and the claims to be made for the drug.
19. contra-indications.

20. toxicity or the side-effects.

21. any directions for the use to be included in the labelling, warning and precautions in use : symptoms of over dosage should be given alongwith the treatment including antidotes, where required.

Proposed route of administration.

Description of the method of manufacture and quality control with details of the equipment.

Specifications, with details of analytical procedure for each ingredient and the finished drugs (not required in case of a drug for which pharmacopocial standards recognised under the Drugs Act, 1976, are claimed).

Bio-availability, Bio-equivalence and Pharmacokinetics Analysis (For Dosage Form Introducing first time in Pakistan).

Stability Summary :

A complete description of and date derived from studies on the stability of new drug, including information pertaining to the suitability of the analytical methods used

Shelf-life when stored under expected or directed storage conditions.

Recommended storage conditions and expiration date to be assigned to the specific formulation and package..

Extreme Temperature Fluctuations Study for all liquid and semi-solid preparations. (Such observations should be utilized for appropriate labelled storage conditions or warning statements).

Type of container/package, with the nature of material, package testing (chemical, mechanical, environmental).

Labelling : Specimen or draft with colour scheme, alongwith the undertaking to refrain from counterfeiting shall also be submitted.

Pack size (s) and proposed maximum retail price with the following details:-

Cost per retail pack of each active and non-active. Ingredients :

Cost of each packing material.

Cost of direct labour,

Justification : (Only in case of a new entity).

Patent number, if any, with date and its date of expiry.

In case of a new drug (entity) not yet registered in Pakistan :

enclose certificate of registration and Free Sale from any of the following countries: Japan, USA and European Company Member countries.

Any other relevant information that may be required by the Board for consideration of this application.

FORM -5(A)

[See rule 26 (1)]

APPLICATION FORM FOR REGISTRATION OF AN IMPORTED DRUG

I/We .....of .....hereby apply for registration of the drug,

namely.....details of which are enclosed.

Date .....

Place ..... Signed.....

ENCLOSURES OF THE APPLICATION FOR REGISTRATION OF A DRUG

Name, address and status of the applicant:

Name and address of the manufacturer:
Name of the drug:

` □Ā Ā Generic international non-proprietory name:

` □Ā Ā Proprietory name, if any:

Name of drug, under which it is proposed to be sod:

Dosage form of the drug:
Composition of the drug stating quantity of each active and non-active ingredients per unit dose or percentage of total formulation:

Proposed dosage:

for adults.

children by age group.
infants.

special groups,

Main Pharmacological group to which the drug belongs:

Proposed route of administration:

Pharmacological and clinical data :

recommended clinical use and the claim to be made for the drug.

contra-indications.
toxicity or the side-effects.

any directions for. use to be included in the labelling warnings and precautions in use: symptoms of overdosage should be given alongwith the treatment including antidotes where required.

Specifications with details of analytical procedure (not required in case of a drug for which the pharmacopocial standards recognised under the Drugs Act, 1976 are claimed):

Bio-availability studies:

Stability studies :

Proposed shelf life with storage conditions, if any :

15 Type of container :

Labelling : (Specimen to be enclosed alongwith a .sample and undertaking to refrain from counterfeiting shall also be submitted) :

Proposed C and F and maximum retail price (in case of imported drug) :

Justification :

Certificate regarding sale and G.M.P. in the country of origin (in English and in Form 5 (c)
Certificate of registration by F.D.A. of USA. Committee on Safety of Medicines of U.K. or corresponding agencies of France, West Germany, Japan, Sweden. and Denmark.

Patent number, if any, with date and its date of expiry :
Undertaking to manufacture drug locally within two years. If it is not possible, the reasons therefor.

FORM-5B

[See rule 26(3A)]

APPLICATION FORM FOR RENEWAL OF REGISTRATION OF ALL KINDS OF DRUGS

I/We ..... of ..... hereby apply for renewal of registration of the drug, namely .....details of which are as follows •

Name and address of the manufacturer:

Name and address of the agent or indentor in case of imported drug -
Whether the drug is registered for local manufacture or import •

Name of the registered drug, with its registration number and date or initial ,registration and last renewal '

Changes, if any, in information furnished at the time of initial registration or last renewal

If withdrawn from the market anywhere •
Country.

Reasons thereof.
Place..... Signature .....

Date..... Name, and address of the signatory .....

FORM-5C

TO WHOM IT MAY CONCERN CERTIFICATE OF DRUGS REGISTERED UNDER THE DRUGS ACT, 1976

Name and dosage form of product .....

Name and amount of each active ingredient

.....

Manufacturer and or when applicable the person responsible for Placing the Product on the

market ..... Address(es).....

It is certified :

Ā Ā This product has been authorised to be place of the market for use in this country. *Number of Registration and date of issue if plicable.
*This product has not been authorised to be placed on the market for use in this country for the following reason-

.....

.....

.....

.....

It is also certified that (a) the manufacturing plant in which the product is produced is subject in inspections at suitable intervals, and (b) the manufacturer conforms to requirements for good practices in the manufacture and quality control, in respect of products to be sold or distributed within the country of origin or to be exported.

(Signature of designated authority (Place and date)

FORM 6

[See rules 28 and 29(4)]

GOVERNMENT OF PAKISTAN

CERTIFICATE OF REGISTRATION

Certified that following drug(s) are hereby registered under the Drugs Ordinance/Act, 1976:-
Name of Drug(s).

Name of Manufacturer.

Name of Indenter/Manufacturer's agent/Importer (in case of imported drugs only).

This registration shall be valid for a period of five years unless earlier suspended or cancelled.

This registration is subject to the conditions specified in the Drugs Ordinance/Act, 1976, and .the rules thereunder and to the conditions specified in the enclosure.

Date of Registration Secretary Registration Board (Seal) Chairman. Registration Board

FORM 7

[See rule 30(6)]

STATEMENT SHOWING QUARTERLY PRODUCTION TO BE SUBMITTED IN DUPLICATE Name of drug. _____

Pharmacological group _____

Name of the Firm. _____

Address. _____

For the quarter ending. _____

Pack size. No. of Pack Total quantity in terms of individual units e.g., total No. of tablets, injections tubes litres etc.

1 2 3

VALUE (in Rs.) Details of Disposal

On trade price On retail price Indicate whether supplied through normal distribution, channels or exported or supplied to any specific institution. Value of raw materials used (Active & inactive) (in Rs.)

4567

Total.

SCHEDULE B

CONDITIONS FOR GRANT OF A LICENSE TO MANUFACTURE BY WAY OF FORMULATION

SECTION-I

PREMISES

Location and Surroundings .

1 Location

2 Surroundings

Building Layout And Its Pre -Approval3. Building Design And Construction (General)

1 General
2 Services

Ā ॅ 3 Protection Against Insects etc.

4 Surfaces

Storage Areas

1 Capacity

2 Design

3 Bays

4 Quarantine

5 Sampling

6 Rejected Materials

7 Special Materials

8 Packaging Materials

3.9 Weighing Area

4. Production Department
5.1 General Facilities

6.2 Dedicated Facilities for Production

7.3 General Requirements for Production Areas

(i) Layout (ii)
Adequacy
(iii) Surfaces
(iv) Services

(v) Drains

(vi) Environmental Controls
(vii) Packaging

(viii) Light

8. Ancillary Areas
9.1 Rest Rooms

10. 2 Changing Rooms

11. 3 Workshops
12. 4 Animal House

SECTION--2

EQUIPMENT FOR PRODUCTION

2.1 General

2.2 Layout

2.3 Construction

2.4 Piping

2.5 Tanks

2.6 Filters

2.7 Cleaning Equipment

2.8 Defective Equipment

SECTION--3

QUALITY CONTROL DEPARTMENT

3.1 General

3.2 Laboratories

3.3 Areas

3.4 Facilities

13. Equipment
14. Others
15. Written Procedures
16. Validation
17. Storage

SECTION--4

DOCUMENTATION

4.1 General

4.2 Specification & Testing Procedures

18. Reference Books

19. Testing Procedures
20. Specifications

4.3 Specifications for Starting and Packaging Materials

4.4 Specifications for Finished Products

4.5 Master Formula

4.6 Packaging Instructions

4.7 Standard Operating Procedures (SOPs) and Records

4.8 S.O.Ps for Testing

4.9 S.O.Ps for Sanitation

4.10 S.O.Ps Miscellaneous

4.11 Labels

4.12 Batch processing records

SECTION--5

SANITATION AND HYGIENE

5.1 Sanitation

5.2 Hygiene

SCHEDULE B-I

[See rule 16 (6) (b)]

REQUIREMENTS OF PLANT AND EQUIPMENT

21. The following equipment is required for the manufacture of drugs for external appliances or suspense:

(1) Mixing tanks where applicable:

(2) Kettles, steam, gas or electrically heated.

(3) A suitable power driven mixer.

(4) Storage tanks or pots.

(5) A calloid mill or a suitable emulsifier or homogeniser, where applicable.

(6) A triple-roller mill or an ointment mill, where applicable.

(7) Liquid filling equipment.

(8) Jar or tube filling equipment, where applicable.

Area of minimum of 200 square feet is required for the basic installation.

22. The following equipment is required for manufacture of Syrups, Exlixirs and Solutions :--

(1) Mixing and storage tanks.

(2) Mixer.

(3) Filter press or other suitable filtering equipment such as metafilter or sparklet filter or Also-pad filter.

(4) Water still or Deioniser.

(5) Various liquid measures and weighing scale.

An area of maximum 300 square feet is required for the basic installations.

23. Equipment for the manufacture of Pills and Compressed Tablets including Hypodermic Tablets. For efficient operation, the tablet production department shall be divided into the following three distinct and separate sections situated in different rooms,

(i) Granulating Section;
(ii) Tableting Section;
(iii) Coating Section.

The following equipment is required in each of the three sections :-

1. Granulating Section: (1) Disintegrator, where applicable.

24. Power Mixer or granulation mixer with stainless steel cabinet
(3} Granular

25. Oven thermostatically controlled.

2. Tableting Section:

26. Tablet machine, single punch or rotary.
27. Pill machine, where applicable.

28. Punch and dyes storages cabinet.

The Tableting Section shall be free from dust and floating particles. For this purpose, it is desirable that each tablet machine is connected either to an exhaust system or isolated into cubicles.

3. Coating Section:

29. Jacketed kettle, or equivalent steam, gas or dect£1cally heated for preparing solution.

30. Coating pan.
31. Polishing pan, where applicable,

{4) Heater and exhaust system, where applicable.

The coating section shall be made dust-free and suitable exhaust provided to remove excess powder and the fumes resulting from solvent evaporation.

A total area of not less than 900 square feet for the three Sections is required for basic installations.

The manufacture of Hypodermic Tablets shall be conducted under aseptic conditions in a separate air-conditioned room, the walls of which shall be smooth and washable. The granulation, tableting and packing shall be done in this room.

32. The following equipment is required for the manufacture of Powders :--

(1) Disintegrator, where applicable.

(2) Mixer.

(3) Sifter or sieve.

(4) Stainless steel vessels and scoops of suitable material,

(5) Filling equipment,

In the case of operations involving floating particles of fine powder or dust a suitable exhaust system shall be provided, Workers shall be provided with suitable marks during operation.

If a manufacturer has e tablet section where the powder of the granules can be manufactured, provided that such granules or powder or non toxic, no separate equipment will be required for manufacture of such powder as granules.

33. The following equipment is required for filling of Hard Gelatin Capsules:-

(1) Mixing and blending equipment.

(2) Capsule filling units.

An area of minimum of 200 square feet is required for the basic installations. The room shall be air-conditioned and also dehumidified wherever necessary.

34. The following equipment is required for ,the manufacture of Surgical Dressings other than Absorbent Cotton Wool

(1) Rolling machine.

(2) Trimming machine.

(3) Cutting equipment.

(4) Folding and pressing machine for gauze.

(5) Mixing tanks for processing medicated dressings.

(6) Hot air drying ovens.

(7) Steam steriliser or dry heat steriliser.

An area of minimum of 300 square feet is required for the basic installations. In case medicated dressings are to be manufactured, room with an area of minimum of 300 square feet shall be provided.

35. The following equipment is required for the manufacture under aseptic conditions of Eye - Ointments, Eye-Drops, Eye-Lotions and other use :-
36. Hot air oven electrically heated with thermostatic control.
37. Kettle, gas or electrically heated with suitable mixing arrangement.

38. Colloid mill or homogeniser.
39. Tube filling equipment.

40. Mixing and storage tanks of stainless steel or of other suitable material.
41. Sintered glass funnel, seitz filter or filter candle.

42. Liquid filling equipment.

43. Autoclave.

An area of minimum of 250 square feet is required for the basic installation. The manufacture and filling shall be carried out in art air-conditioned room under aseptic conditions. The room shall be further dehumidified if preparations containing antibiotics are manufactured.

44. The following equipment is required for the manufacture of Pessaries and Suppositories : -

(1) Mixing and pouring equipment.

(2) Moulding equipment.

An area of minimum of 200, square feet required far the basic installation,

In case of pessaries manufactured by granulation compression, if the licence does not have a tablet section, a separate area of minimum of 300 squared feet and the following equipment is necessary :--

45. Mixer.

46. Granulator.
47. Drier.

48. Compressing machine.
49. Pessary and tablet counter.

50. The following equipment is required for the manufacture of inhalers end Vitrallae:

(1) Mixing equipment.

(2) Graduated delivery equipment for measurement of the medicament.

(3) Sealing equipment,

An area of minimum of 200 square feet is required for the basic installations.

51. The following equipment is required for the repacking installation of drugs and Pharmaceutical Chemicals

(1) Sifter.

(2) Stainless steel scoops end vessels.

(3) Weighing and measuring equipment.

(4) Filling equipment.

An area of minimum of 300 square feet is required for basic packing operations. In the case of operations involving floating particles of fine powder or dust, a suitable exhaust system should be provided.

52. Requirements for the manufacture of Parenteral Preparations: The whole process of the manufacture of parenteral preparations may be divided into the following separate operations:

53. Preparations of the container: This includes, cutting. washing, drying sterilisation of ampoules or vials prior to

54. Preparation of solution: This includes preparation and filteration of solution.
55. Filling and sealing: This includes filling and sealing of ampoules or filling and capping of vials.

56. Sterilisation.

57. Testing,
The following basic hygienic requirement shall be complied with

58. Strict sanitation shall be maintained throughout the entire plant in order to prevent contamination and to keep out pyrogens, Masks end overalls shall be worn wherever necessary.

59. The preparation room w here the solution ate prepared shall be of such a nature that may be kept scrupulously clean. This room shall be air-conditioned.

60. The filling and sealing rooms shall likewise be air-conditioned under positive pressure with air locks provided to. prevent, the entry of air from outside. The walls and floor shall be such as may permit their being sprayed and washed with an antiseptic solution. The benches shall preferably have stainless steel or laminated plastic tops capable of being washed.

61. In the room provided for aseptic filling and sealing, necessary measures for maintaining sterility and to preventing contamination shall be adopted.

62. A separate room shall be provided .for sterilisation, testing (for leaks and floating particles) and dryin

63. Finished products shall be stored in a suitable separate place.

The following equipment required :-

Manufacturing Area :

64. Storage equipment for ampoules and vials
65. Ampoule washing and drying equipment.

66. Dust proof storage Cabinets.
67. Water still.

68. Mixing and preparation tanks or other containers. The tanks or containers shall be made of either glass or such material which will not react with the liquid

69. Filtering equipments such as filter press or sintered glass funnel.
70. Autoclave,

71. Hot Air Steriliser,

Filling and Sealing Room:

72. Benches for filling and sealing.
73. Filling and sealing unit

Aseptic Filling and sealing room:

74. Bacteriological filters such as Seitz filter, candles or sintered glass filters,
(12} Filling and. sealing unit,

General Room:

75. Inspection table with draft and light background

76. Leak tasting equipment.

77. Labelling and packing benches,
78. Storage equipment including cold storage and refrigerators, if necessary

Note /: The above requirements of this schedule are subject to modifications, at the discretion of the Central Licensing Board if it is of the opinion that having regard to the nature and extent of the manufacturing operations it is necessary to relax or alter in the circumstances of a particular case:

Provided that such variation shall be recorded in writing with reasons therefor and also communicated in writing to the manufacturer for his record,

Note//: This Schedule gives equipment and space required for certain categories of drugs only. There are, in addition, other categories such as drugs miscellaneous pharmaceuticals such as Ferries Ammonii Citras. Potassium Citras, Glycerin, Paraffin, Oxygen gas, Disinfectant fluids, mechanical contraceptives, surgical cotton and tinctures which are not listed in this Schedule. The Central Licensing Board shall, in respect of such categories of drugs, have the discretion to examine the adequacy or otherwise of factory premises, space, plant, machinery and other requirements having regard to the nature and extent of the manufacture to carry out necessary modifications in them and, on the modification. having been made, approve of the manufacture of such categories of drugs. Any drug so permitted to be manufactured by the Central Licensing. Board shall be d eemed to be an additional category of drug for the purpose of this Schedule.

SCHEDULE B I-A.

[See rule 16 (bb)-7]

CONDITIONS OF FACTORY PREMISES

79. Location and surrounding: The premises should be away from drinking water sources and an area liable to flooding.

80. (a) Building: Building should be provided with both good general ventilation and protection against direct sunlight, with easy access for fire -fighting equipment including fire-extinguishers, fire-blankets, .hose, reels and fire -alarm, etc. Sufficient water must be available for fire-fighting.

(b) Wells: Walls as far as possible should be protected by non-flammable or slow burning material.

(c) Doors; Doors must be fire resistant preferably with self-closing system,

(d) Floors: Floors should be impermeable to liquids, smooth and free from cracks. There should be no drains at all in plants and in warehouse. If drains are absolutely necessary they must not contract directly with waterways or public sewers,

(e) Signs: Signs indicating smoking restrictions, location of emergency kits, fire-fighting equipment, telephone end escape routes must be prominently displayed. Local exhaust system must be effective,.

81. Personnel: To void intoxication by skin contact, inhalation of fumes, vapours and dust, accidental ingestion, the protected clothing and equipments, e.g., protective helmet or cloth cap, eye protection (safety spectacles, goggles or face shield) dust or light fume masks, one piece worksuit with closely fitting trouser bottoms, rubber or plastic gloves Or gauntlets, rubber or plastic apron, and workboots with protective toecaps, must be provided.

Staff must not be allowed to go home wearing the same clothing they wore at work; emergency showers and eye washing facilities must be provided in the premises. Safety instructions should be strategically displayed in local language. All emergency and safety equipment must be frequently and regularly checked and maintained to ensure its conditions satisfactory.

82. Medical Services: There must be pre-employment medical; , examination for all staff members whether working permanently or on contract basis. When organophosphates or carbamates are handled, pre -exposure baseline blood cholinesterase level must be determined for all operational staff. Staff regularly engaged in formulation and packing procedures and maintenances must have their cholinesterase levels checked regularly and detailed records must be kept. The checks should be carried .out by a properly equipped hospital or laboratory under qualified expert.

"Levels of cholinesterase activity should be interpreted by a doctor, but the following guide might be helpful :--

83. A decease of more than 20% in blood cholinesterase activity,. from the pre -exposure value indicates that the cause should be investigated.

84. A decrease of more than 40% in blood cholinesterase activity from the pre -exposure value indicates that the worker concerned should be removed from further exposure to organophosphates or carbamates.

Workers should not be exposed again to cholinesterase inhibiting compounds until further tests show a blood cholinesterase activity within 20% of the pre -exposure value.

SCHEDULE B-II

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SCHEDULE B-III

[See rule 20 (b)]

PARTICULARS TO BE SHOWN IN MANUFACTURING RECORDS
A. Substances Parenteral preparation in general:

97. Serial Number.

98. Name of the
drug. 3, Batch Size,

99. Batch number.
100. Date of commencement of manufacture and date when manufecture was completed,

101. Name of all ingredients, quantities required for the batch size, quantities actually used. (All weighings and measurements shall be checked initiated b¥ the competent person in the section).

102. Control reference numbers in respect of raw materials used in formulation.
103. Date of mixing in case of dry products, e.g., powder, powder mixture for capsule products, etc.

104. Date of granulation wherever applicable.
105. Weight of granules.

106. Date of compression in case of tablets/date of filling in case of capsules.
107. Dates of coating wherever applicable.

108. Records of test to be carried out in case of tablets as under
(a) Average weight every thirty minutes.

(b) Disintegration time as often as practicable.

109. Records of readings taken to check weight variation in case of capsules,
110. Reference to Analytical Report number stating whether of standard quality or otherwise. 16, Records on the disposal of rejected batches and batches with-drawn from the market. 17, Actual production and packing particulars indicating the size and quantity of finished packings,

111. Date of release of finished packings for distribution or sale,
112. in case of Hypodermic tablets and ophthalmic preparations which are required to be manufactured under aseptic conditions, records shall be maintained indicating the precautions taken during the process of manufacture to ensure that aseptic conditions are maintained,

113. Signature of the expert staff responsible for the manufacture,

B. Parenteral preparation:

114. Serial Number,
115. Name of the drug,

116. Batch Size,

117. Batch number (if bulk lot is divided into various batches and processed separately, a batch number distinctly different from that of the bulk lot should be assigned to each of the processed batch),

118. Date of commencement of manufacture and date of completion.

119. Name of all ingredients, quantities required for the lot size, quantities actually used. (All weighings and measurements shall be checked and initialled by the competent person in the section).

120. Control reference numbers in respect of raw materials used.
121. PH of the solution wherever applicable.

122. Date and methods of filtration.
123. Sterility test reference on bulk batch wherever applicable. (If bulk lot is divided into various batches and processed separately, a batch number distinctly different from that of the bulk lot should be assigned to each of the processed batch.

124. Date of filling.

125. Records of tests employed :--

126. To ensure that sealed ampules are leak-proof,

127. To check the presence of foreign particles.
128. For pyrogens wherever applicable.

129. Records of sterilisation in case of parenteral preparation which are heat sterilised including particulars of time temperature and pressure employed.

130. Number and size of containers filed and number rejected.
15, Reference to Analytical Report numbers stating whether of standard quality or otherwise.

131. Records of the disposal of rejected batch and batches with-drawn from the market.
132. Actual production and packing particulars.

133. Date of release finished packings for distribution or sale.

134. Particulars regarding the precautions taken during manufacture to ensure that aseptic conditions are maintained.

135. Control reference numbers in respect of the lot of glass containers used for filling.
136. Signature of the expert staff responsible for manufacture.

II. RECORDS OF RAW MATERIALS

Records in respect of each raw material shall be maintained indicating the quantity received, control reference numbers, the quantities issued from time to time, the names and batch Nos. of the products for the manufacture of which the quantities have been issued and the particulars relating to the proper disposal of the stocks.

137. PARTICULARS TO BE RECORDED IN THE ANALYTICAL
RECORDS A. Tablets and capsules:
1. Analytical report number.

2. Name of the sample.

3. Date of receipt of sample,

4. Batch number.

5. Protocols of tests applied:

(a) Description.

(b) Identification.

(c) Uniformity of weight.

(d) Uniformity of diameter (if applicable).

(e) Disintegration test (time in minutes).

(f) Any other tests.

(g) Results of assay.

Note: Records racer, cling various tests applied (including reading and calculation) should be maintained and necessary reference to these records should .be entered in serial No. 5 whenever necessary.

138. Signature of the Analyst.
139. Opinion and signature of the approved Analyst.

B. Parenteral Preparations

140. Analytical report number.

141. Name of the sample.
142. Batch number.

4, Date of receipt of sample.

143. Number of containers filled.

144. Number of container packed

145. Protocols of tests applied
(a) Clarity,

(b) PH wherever applicable,

(c) Identification.

(d) Volume in container,

(e) Sterility--(/) Bulk sample wherever applicable (ii) container sample.

(f) Pyrogen test, wherever applicable.

146. Toxicity test, wherever applicable.

147. Any other teats.
148. Results of assay.

Note: Records regarding various tests applied (including readings and calculations)should be maintained and necessary reference to these records should be entered in Serial No.7. wherever necessary

8. Signature of the Analyst.

9, Opinion and signature of the approved Analyst Pyrogen Tests:-

149. Test Report number.

150. Name of the sample.

151. Batch number.
152. Number of rabbits used.

153. Weight of each rabbit.
154. Normal temperature of each rabbit.

155. Mean initial temperature of each rabbit,
156. Dose and volume of solution injected into each rabbit and time of injection.

157. Temperature of each rabbit noted at suitable intervals,

158. Maximum temperature.
159. Response.

160. Summed response,
161. Signature of the Analyst,

162. Opinion and signature of the approved Analyst

Toxicity Test:

163. Test Report number.
164. Name of
the Sample 3, Batch
number

165. Number of mice used and weight of each mouse, Strength and volume of the drug injected, 6, Date of injection,

166. Results and remarks,
167. Signature of Analyst,

168. Opinion and signature of the approved Analyst.

C. For other drugs:

1.Analytical report number

169. Name of the sample

170. Batch number.
4, Date of receipt of sample

171. Protocols of tests applied:

(a) Description.

(b) Identification.

(c) Any other tests

(d). Results of assay.

Note: Particulars regarding various tests applied (including reading and calculations) shall be maintained and necessary reference to these records shall be entered in s erial No. 5 wherever necessary.

172. Signature of the Analyst.

173. Opinion and signature of the approved Analyst.

D. Raw materials:

174. Serial number

175. Name of the material

176. Name of the manufacturer/supplier.
177. Quantity received.

178. Invoice/Challan number and date.

179. Protocols of tests applied.
Note: Particular regarding various tests applied (including reading and calculations) shall be maintained and necessary reference these records shall be entered in serial No. 6 wherever necessary.

E. Container, packing material, etc.:

180. Serial number.
181. Name of the item.

182. Name of the manufacturer/supplier.
183. Quantity received.

184. Invoice/Challan number
and date. 6, Results of tests applied.

Note: Particulars regarding various tests applied shall be maintained and necessary reference to these records shall be entered serial No. 6 wherever necessary.

185. Remarks.
186. Signature of the examiner.

Note I: The foregoing provisions represent the minimum requirements to be complied with by the licensee. The Central Licensing Board may, however, direct the nature of records to be

maintained by the licensee for such drugs as are not covered by the categories described in this Schedule.

Note 2: The Central Licensing Board may permit the licensee to maintain records in such manner as are considered satisfactory, provided the basic requirements laid down in the Schedule are complied with.

Note 3: The Central Licensing Board may as its discretion direct the licensee to maintain records for such additional particulars as it may consider necessary in the circumstances of a particular case.

SCHEDULE C

[See rule 16(c) (iii) and (e)]

187. Sera.

188. Solution of serum proteins intended for injunction.
189. Vaccines.

190. Toxins.
191. Antigen.

192. Antitoxins.
193. Insulin.

194. Pituitary (Posterior Lobe) Extract.

195. Sterilized surgical lignature and sterilized surgical suture.
196. Bacteriophages.

SCHEDULE D

[See rule 17(1)]

DRUGS FOR REPACKING

197. Alniminium Hydroxide Gel Dried.

198. Ammonium Bicarbonate.
199. Ammonium Chloride.

200. Ammonium Carbonate.
201. Benzoic Acid.

202. Bismuth Carbonate.

203. Bismuth Subnitrate.
204. Boric Acid.

205. Borax.

206. Caffein and its Salts.
207. Calamine.

208. Calcium Carbonate.
209. Calcium Lactate.

210. Calcium Gluconate.

211. Calcium Hydroxide.
212. Castor Oil.

213. Cetrimide Powder.
214. Chloral Hydrate.

215. Ephedrine Hadrochloride.
216. Ephedrine Sulphate.

217. Ferrous Sulphate.

218. Ferric Ammonium Citrate.
219. Gentian Violet.

220. Glycerin.
221. Iodine.

222. Ichthammol.

223. Kaolin.
224. Liquid Paraffin Heavy.

225. Magnesium Carbonate.
226. Magnesium Hydroxide.

227. Magnesium Sulphate.
228. Methylene Blue.

229. Magnesium Trisilicate.

230. Methyl Salicylate.
231. Phenothlazine (B. VET. C.).

232. Pix Carb.
233. Potassium Acetate.

234. Potassium Bromide.

235. Potassium Bicarb.
236. Potassium Chloride.

237. Potassium Citrate.
238. Potassium Iodine.

239. Potassium Permanganate.
240. Procaine Hydro-Chloride.

241. Pulv Gentian.

242. Resorcin.
243. Salicylic Acid.

244. Sentonin.
245. Sena.

246. Sodium Benzoate.

247. Sodium Bicarbonate.
248. Sodium Chloride.

249. Sodium Bromide.
250. Sodium Carbonate.

251. Sodium Citrate.
252. Sodium Iodide.

253. Sodium Metabisuphite.

254. Sodium Potassium Tartrate.
255. Sodium Salicylate.

256. Sodium Sulphate.
257. Sodium Thiosulphate.

258. Soft yellow Paraffin.

259. Sulphonilamide Powder (B. VET. C).
260. Sulphur Precipitated.

261. Sulphur Sublime.
262. Tannic Acid.

263. Zinc Oxide.

264. Zinc Sulphate.

SCHEDULE D-I
[See rule (31)1]

Household remedies including--

Analgesics:

Aspirin and Paracetamol in tablets and liquid forms.

265. Analgesic Balms/Plasters.

266. Antiseptics and disinfectants for household use, excluding those containing hormone and antiniotics.

267. Antidandruff preparations.

268. Dental preparations.
269. Antacid and carminatives:

Compound Effervescent Salts, [--] , Milk of Magnesia.

(7)

270. Contraceptives.
271. Miscellaneous.

Fish Liver Oil and its equivalents.

SCHEDULE E

[See rule 31 (10)]

DISEASES, ADVERTISEMENT FOR TREATMENT OF

WHICH IS PROHIBITED

272. [Omitted vide S.R.O. 871(I)/78, dated 8th July, 1978.]
273. [Omitted vide S.R.O. 871(I)/78, dated 8th July, 1978.]

274. Venereal diseases.
275. Sexual importance.

276. Amenorrhoea metrorrhagia, memorthagia, metrosalpingitis, ovaritis, fibromas, cysts.
277. Bright's disease, cataract, glaucoma, epilepsy, [...] lacomotive ataxia, multiple sclerosis, lupus, paralysis, blindness.

278. Complaints requiring surgical operation (e.g., appendicitis, stomach ulcers, prostatic disorders, hernias, sinusitis, mastodities.

279. Serious illness liable to endanger the life of the patient (e.g., pneumonai, pleurisy, abscess of the lungs).

280. Gripe Waters.

281. Cough Preparations.

SCHEDULE F

[See rule 5 (2)]

282. DRUG MANUFACTURING LICENCE FEE

(a) For the grant of licence:
Type of licence Fee

By way of basic Rs. 10,000By way of semi-basic Rs. 10,000
By way of formulation Rs. 25,000

By way of repacking Rs. 15,000

(b) For the renewal of licence

283. If the application for renewal if made before the expiry of period of validity of licence. Type of licence Fee

By way of basic Rs. 5000By way of semi-basic Rs. 5,000
By way of formulation Rs. 12,500

By way of repacking Rs. 7,500

284. If the application for renewal is made after the expiry of the period of validity of licence but within sixty days after expiry of the period validity:

Type of licence Fee

By way of basic Rs. 10,000By way of semi-basic Rs. 10,000
By way of formulation Rs. 25,000

By way of repacking Rs. 15,000

285. DRUG
REGISTRATION FEE [See
rule 26 (3)]
(A) For the grant of Registration Rs. 5,000

(B) For the renewal of Registration

(i) if the application for renewal is made before the expiry of the validity of a certificate Rs. 2,500

(ii) if the application for renewal is made within thirty days after the expiry of the period of validity of a certificate

Rs. 5,000

III. FEE FOR ADVERTISEMENT
[See rule 31 (1A) and (1B)]

Application fee for Advertisement. Rs. 1,000 per advertisement

SCHEDULE G

[See rule 30 (11)]

ETHICAL CRITERIA FOR MEDICINAL DRUG PROMOTION

286. Promotion of drugs.- (1) For the purposes of this Schedule, "promotion" means all informational and persuasive activities by manufacturer and distributors, the effect of which is to induce the prescription, supply, purchase and/or use of medicinal drugs.

287. All claims concerning a drug for the purposes of promotion shall be reliable, accurate, truthful; informative, balanced, up to date, capable of substantiation and in good taste. Such claims shall not contain misleading, unverifiable statements, omissions likely to induce medically unjustifiable use of a drug or to give rise to under risks. The word "safe" shall not be used with respect to promotion unless properly qualified. Comparison of products shall be factual, fair and capable of substantiation. Promotional material shall not be designed so as to disguise its real nature.

288. Scientific data in the public domain shall be made available, on request, to prescribers and any other person entitled to receive it as appropriate to their requirements. Promotion in the form of financial or material benefits shall not be offered to or sought by health care practitioners to influence them in the prescription of drugs.

289. Advertisements in any form made to physicians and health-related professionals.- (1) The wording and illustrations in advertisements to physicians and related health professionals shall be fully consistent with the approved scientific data sheet for the drug concerned or other source of information with similar content. The text shall be fully legible.

(2). While introducing the drug to the physician for the first time in shall contain full product information, on the basis of the approved scientific data sheet or similar document and shall contain, among others, the following information:-

290. The generic name(s) of the active ingredient(s);
291. the content of active ingredient(s) per dosage form or regimen;

292. the generic name(s) of other ingredient(s) known to cause problem(s)
293. the approved therapeutic uses;

294. dosage form or regimen;

295. side-effects and major adverse drug reactions;
296. precautions, contra-indications and warnings;

297. major interactions;
298. the name and address of manufacturer or distributor; [--]

299. reference to appropriate scientific literature ; and
300. Price of the drug, ; and

301. Reminder advertisements shall include, amongst others, at least the international non-proprietary name or generic name , the name of each active ingredient and the price of drug

and the name and address for the manufacturer or distributor for the purpose of receiving further information.

302. Advertisements in any form to the general public.- (1) Advertisements to the general public, where permissible, shall help people to make rational decisions on the use of drugs determined to be legally available without a prescription. While advertisements shall take account of people's legitimate desire for information regarding their h ealth they shall not take undue advantage of people's concern about their own health. Advertisement shall not generally be permitted for prescription drugs or to promote drugs for certain serious conditions that can be treated only by qualified health practitioners. The scheduled narcotic and psychotropic drugs shall not be advertised to the general public in connection with fight against drug addiction and dependency. Although health education aimed at children is highly desirable, drug advertisements shall not be directed at children. Promotional material shall be factual and claims for cure, prevention or relieve of an ailment shall be made only if this can be substantiated. Advertisements shall also indicate, where applicable, appropriate limitations to the use of the drug.

303. When lay language is used the information shall be consistent with the approved scientific data or other legally determined scientific basis for approval. Language which brings about fear or distress shall not be used.

304. Taking into account the media employed, advertisements to the general public may amongst others, contain, he following information:-

(a) The generic name(s) of the active ingredient(s);

(b) major indication(s) for use; (S.R.O. 1362(I)/96-28.11.96).

(c) major precautions, contra-indications and warnings, if any; and

(d) name of manufacturer or distributor.

4. Information on price to the consumer shall be accurately and honestly portrayed.

305. Medical Representatives.- (1) Medical representatives shall have an appropriate educational background. They shall be adequately trained so as to posses sufficient medical and technical knowledge and integrity to present information on products and carry out other promotional activities in an accurate and responsible manner. Employers shall be responsible for the basic and continuing training of their representatives. The training shall include instructions regarding appropriate ethical conduct taking into consideration the W.H.O. criteria.

306. Medical representatives shall make a vailable to prescribers and dispensers complete and unbiased information for each product discussed, such as an approved scientific data or other source of information with similar contents.

307. Employers shall be responsible for the statements and activities of their medical, representatives. Medical representative shall not offer inducements to prescribers and dispensers. Prescribers and dispenses shall not solicit such inducements. In order to avoid over-promotion, the main part of the volume of sales they generate.

308. Free samples of prescription drugs for promotional purposes.- Free samples of drugs may be provided in modest quantities to prescribers, preferably on request.

309. Free samples of non-prescription drugs to the general public for promotional purposes.-There shall be no free sampling of non-prescription drug to the general public for promotional purposes.

310. Symposia and other scientific meetings.- The intimation regarding scientific symposia, seminars, conferences and such meetings where sponsored by a pharmaceutical manufacturer or distributor shall be clearly communicated in advance. The invitation letter should accurately

reflect the presentations and discussions to be held. Entertainment or other hospitality, offered to members of the medical and allied professions shall be secondary to the main purpose of the meeting and shall be kept to a modest level.

311. Post-marketing scientific studies, surveilance and disseminaion of information.- (1) The Registration Board shall be made aware of any post-marketing clinical trials for drugs that are conducted and the results thereafter as soon as possible.

312. Post-marketing scientific studies and surveillance shall not be misused as a disguised form of promotion.

313. Substantiated information on hazards associated with the drug shall be reported to the Registration Board as a priority.

314. Packaging and labelling.- Appropriate information being important to ensure the rational use of drugs, all packaging and labelling material shall provide information consistent with that approved by the Registration Board and if no such approval is available it shall be, consistent with that approved by the drug regulatory authority of the country from which the drug is imported or other reliable sources of information with similar content. Any wording and illustration on the package and label shall conform to the principles of ethical criteria enunciated in this Schedule.

315. Information for patients contained in package inserts, leaflets and booklets.- (1) Adequate information on the use of drugs shall be made available to the patients where it is necessary for rational use of a drug. In package inserts or leaflets the manufacturers or distributors shall ensure that the information reflected is correct. If package inserts or leaflets are used for promotional purposes, they shall comply with the ethical criteria enunciated in this Schedule. The wording of the pcakge inserts or leaflets, if prepared specially for patients, shall be in lay language subject to the condition that the medical and scientific content is properly reflected.

316. In addition to approved package inserts and leaflets wherever available the preparation and distribution of booklets and other information material for patients and consumer shall also comply with the ethical criteria enunciated in this schedule.

[No. F. 8-1/90--AU (Vol-11.)]

DR. F.R.Y. FAZLI,

Deputy Director General (Pharmacy)/Drugs Controller.

(S.R.O. 1362(I)/96 28.11.1997)

The Drugs (Appellate Board) Rules, 1976

S. R. O. 595 (1)/76, dated 2lst June, 1976: In exercise of the powers conferred by Section 43 of the Drugs Act, 1976 (XXXI of 1976), the Federal Government is pleased to make the following rules, the same having been previously published as required by sub-section (3) of the said section, namely :--

317. Short title and commencements: (1) These rules may be called the Drugs (Appellate Board) Rules, 1976.

(2) They shall come into force at once.

318. The Appellate Board: (1) The Appellate Board shall consist of the following members, namely :--
(a) Secretary, Health Division, Government of Pakistan, who shall be its ex-officio Chairman.

(b) Secretary, Health Department, Government of the Punjab, ex-officio or his representative, not below the rank of an officer in BPS 19, who is an expert in machine, pharmacology or pharmacy.

319. Secretary, Health Department, Government of Sind, ex-officio or his representative, not below the rank of an officer in BPS 19, who is an expert in machine, pharmacology or pharmacy.

320. Secretary, Health Department, Government of Baluchistan, ex-officio or his representative, not below the rank of an officer in BPS 19, who is an expert in machine, pharmacology or pharmacy.

321. Secretary, Health Department, Government of the North-West Frontier Province, ex-officio or his representative, not below the rank of an officer in BPS 19, who is an expert in machine, pharmacology or pharmacy.
322. One Professor of medicine, to be nominated by the Federal Government.

323. One Professor of Pharmacology, pharmacology or medicine to be nominated by the Federal Government.

324. One representative of the Law Division, Government of Pakistan.

325. Chairman, Quality Control Authority, Health Division, Government of Pakistan, who shall be its ex-officio Secretary,

326. One representative of the Ministry of Law and Parliamentary Affairs, Government of Pakistan,

327. Chief Cost Accounts Officer of the Ministry of Finance.

328. The members, other than ex-officio members, of the Appellate Board shall hold office for a period of three years and shall be eligible for renominations.

329. The Appellate Board shall meet as and when required to perform its functions.

330. The Appellate Board shall have powers to appoint a Committee of Experts for detailed investigation of any matter and report to the Board.

331. No act or proceeding of the Appellate Board shall be invalid merely on the ground of the existence of any vacancy in, or any defect in the constitution of the Board.

332. Powers of the Appellate Board: The members of the Appellate Board shall exercise all the powers of an Inspector without restriction as to area, and such other powers as may be necessary to perform their functions.

333. Procedure of Appeal: (1) Any person aggrieved by a decision of the Registration Board, the Central Licensing Board or a licensing authority may, within sixty days of receipt Of such decision, submit an appeal to the Appellate Board.

334. An application for appeal under sub-rule (1) shall be in triplicate and be accompanied by a copy of the decision appealed against, and shall contain all material statements and arguments relied on by the appellant.

335. The Appellate Board shall transmit a copy of the application for appeal referred to in sub-rule (2) to the Registration Board or the Central Licensing Board or the licensing authority against whose decision

the appeal has been made. and such Board or authority shall. on demand, produce before the Appellate Board the record of the case leading to the decision.

336. The Appellate Board shall, after giving the appellant an opportunity of being heard, pass such orders as it thinks tit and such orders shall be final.

337. Revision: The Appellate Board may, of its own motion at any time, call for the record of any case for the purpose of satisfying itself as to the correctness, legality or propriety of such order and may pass such order in relation thereto as it thinks fit.

RESEARCH

S.R.O. 1047(I)/78, dated 15th July, 1978: In exercise of the powers conferred by Section 43 of the Drugs Act, 1976 (XXXI of 1976), the Federal Government is pleased to make the following rules, the same having been previously published as required by sub-section (3) of the said section, namely :-

1. Short title and commencement:

338. These rules may be called the Drugs (Research) Rules, 1978.
339. They shall come into force at once,

340. Definitions: In these rules, unless there is anything repugnant in the subject or context,-

(a) "Committee" means the Committee of Experts constituted under rule 8;
(aa) "form" means form appended to these rules;

(b) "Fund" means the Central Research Fund maintained by the Federal Government under sub-rule (14) of rule 19 of the Drugs (Licensing, Registering and Advertising), Rules, 1976;

(c) "investigator" means a person engaged in the investigation, research, development or evaluation of a drug on his own initiative or under the sponsorship of any other person or an institution;

(d) "recipient" means a person or an institution who or which receives aid from the Fund; and

(e) "sponsor" means a person, firm, an establishment or institution promoting research on a drug.

341. Utilisation of Fund: The Federal Government may utilise the Fund for conducting research, development or evaluation of a drug either itself or through a research institution working under its control or disburse it among investigators or institutions for such purposes subject to such conditions as may be specified and for that matter, it may also utilize the fund to upgrade and establish Drugs Research and testing laboratories and a unit in the Drugs Control Section, Ministry of Health, for evaluation and monitoring of the research proposals and projects and management of the fund.

342. Research in drugs: The research in drugs shall be conducted at such place or places and by such person or persons as may be approved by the Federal Government and shall be categorised as under :--

(i) other than clinical trials; and
(ii) clinical trials.

343. Application for grant of aid: (1) An application for the grant of aid from the Fund for conducting research on a drug on aspects other than the clinical trials and for clinical trials shall be made in Form 'A' and Form 'B', respectively, and addressed to the Secretary of the Committee.

(2) The Federal Government may, before granting any aid from the Fund, cause inspection of the premises concerned end technical evaluation of the project by the Committee or any expert appointed by it for this purpose.

(3) The Federal Government may, after obtaining the advice of the Committee and subject to such conditions as it may specify in this behalf, grant such aid from the Fund to a person or an institution as it may deem fit.

344. Conditions for conducting research on aspects of other than clinical trials: (1) The research on any aspect of drugs other than clinical trial shall be conducted under the supervision of an investigator who possesses post-graduate qualification and experience in the relevant field and has sufficient background knowledge to conduct scientific investigation.

(2) The recipient shall, at regular intervals not exceeding six months, submit the progress report to the Federal Government in respect of the investigation being conducted.

(3) No change of an investigator or in the plan for investigation shall be made without prior approval of the Federal Government.

(4) The recipient shall allow an expert or a panel of experts authorised by the Federal Government to visit the premises at which the research is being conducted and to see that the

Fund is being utilised in accordance with the approved plan.

345. Conditions for research in clinical trials: (1) In addition to the conditions laid down in rule 6, research in drugs on aspect of clinical trials shall be conducted in the following stages:-
(i) Stage 1 of investigation on human beings shall consist of studies to determine single and short term multiple dosing for tolerance, side effects, toxicity, metabolism, preferred routes of administration, safe dosage range and other pharmacological actions of the drug:

Provided that these studies shall be conducted under carefully controlled circumstances on comparatively small number of subjects to prevent any serious deleterious effect on health. (ii) Stage II of investigation shall consist of studies to determine safety and effectiveness including an effective dose range, the common side effects of the drug on both clinical and laboratory parameters and where possible the level of drug in biological fluids in relation to therapeutic response:

Provided that these studies shall be undertaken if studies in Stage I of investigation demonstrate satisfactory results and shall involve initial and limited use of the drug in the treatment or prevention of the disease for which the drug is intended and shall be administered to carefully supervised patients:

Provided further that the Federal Governme nt may require additional pharmacological studies to be conducted concurrently on animals to indicate safety for stage II of the investigation. (iii) Stage III of investigation shall consist of studies under controlled conditions in order to expand knowledge of potential use and hazards and shall be undertaken if the data obtained in stages I and II provide reasonable assurance of safety and effectiveness or suggest that the drug may have a potential value of conducting several trials outweighing its hazards:

Provided that these studies shall be carefully monitored and all possible precautions shall be taken to prevent unnecessary exposure of the patient to the risk.

(2) If at any stage there appears to be an unwarranted hazard in the continuation of the ongoing clinical trials, the sponsor and recipient may be asked by the Federal Government to modify or discontinue clinical trials until further pre-clinical work has been done and the investigator conducting such research shall discontinue further tests under intimation to the sponsor and the recipient in writing, a copy of which be sent to the Federal Government.

(3) Studies on children shall not be undertaken unless there is a possibility of benefit to them and adequate studies of safety and efficacy are available in adults.

(4) When any dangerous or adverse effects are observed, emergency reports shall be sent immediately by the recipient to the Federal Government so that the other investigators are informed and the studies are stopped if the hazard so warrants.

(5) The consent for use of all investigational new drugs in clinical trials for stages I and II shall be obtained in writing by the investigator but for stage III it is the responsibility of the investigator to take into consideration the physical and mental state of the patient to decide when it is necessary or preferable to obtain consent other than in writing and if written consent is not obtained, the investigator, must obtain oral consent and record the fact in the medical record of the person receiving the drug.

(6) The recipient shall keep the record of his studies carefully in respect of every drug, retain it for at least ten years after registration of that drug and produce it before the Federal Government whenever required.

346. Committee of Experts on Drug Research: (1) The Federal. Government shall set up a Committee of Experts on Drug Research to determine the priorities, to give directions in drug research, to evaluate the applications received for the grant and make allocations from the

.Fund and to take or propose such actions and measures as may be necessary for ensuring effective and proper use of the Fund:

(1) The Federal Government shall constitute a Committee of Experts to advise it on the utilisation of the Fund and for such other purposes as may be necessary for the proper utilisation of the Fund.

(2) The Committee shall consist of the following members namely :-

(a) Director-General Health who shall be its ex-officio Chairman.

(b) Executive Director, National Institute of Health, Islamabad.

(c) Chairman of the Pharmacy Department who shall hold office for three years by rotation. Chairman, Pharmacy Department, Peshawar University shall be the member for the first term.

(d) Chairman of the Pakistan Council of Scientific and industrial Research or his nominee who

may be directly responsible for drugs research activities in the Council.

347. Chairman of the Pakistan Medical Research Council, or his. nominee who may be directly responsible for drugs research activities in the Council.

348. A Dean of the Pharmacy Faculty who shall hold office for three years by rotation. Dean of the Pharmacy Faculty, University of Karachi, shall be the member for the first term.

349. A Professor of Pharmacology who shall hold office for three years by rotation. Professor of Pharmacology Allama Iqbal Medical College, Lahore, shall be the member for the first term.
350. One representative of the Pakistan Pharmaceutical Manufacturers' Association (PPMA) who may be well-versed with the subject and actively engaged in the planning or conducting of research on drugs.

351. Drugs Controller, Ministry of Health, Islamabad.
352. Deputy Director General Health (Research and Development), Ministry of Health, Islamabad, who shall be its ex-officio Secretary.

(3) The Federal Government may appoint a Secretary of the Committee from amongst its members.

9. Withdrawal of Fund and termination of an investigation: (1) The Federal Government may, at any stage of an investigation, withdraw the aid from the recipient and direct him and the sponsor to terminate a clinical trial under any of the following conditions, namely :-

353. evidence of significant hazard;
354. convincing evidence that the drug is ineffective;

355. submission of false data;
(iv} omission of material information pertaining to safety or efficiency of the drug;

356. unsatisfactory manufacturing practices;
(vi) failure to conduct the investigation in accordance with plan submitted and approved by the Federal Government;

(vii) commercialization of the drug before completing clinical trial;
(viii) failure to report serious or potentially serious adverse reaction;
(ix) failure to meet the requirement of patient's consent; and

357. evidence of misuse of the Fund:

Provided that the Federal Government may, before withdrawing the a id, require the recipient and the sponsor of any drug to comply with any of the above conditions which he has failed to comply within a specified period and may, after it is satisfied that the said conditions have been compiled with, allow resumption of the investigation.

FORM 'A'

[See rule 5 (1)]

Application for grant of aid for conducting research in drugs other than clinical trials

358. Name and address of the applicant.

359. Name and address of the sponsor if he is other than the applicant.

360. Title of Research project.
361. Financial implications of the project.

362. Total Financial implications.
363. Present investment.

364. Other sources of finance. if any
365. Amount required from the Drugs Research Fund and details of its proposed utilisation.

5. Details of the Research project as follows :--

366. Purpose.

367. Outline.
368. Progress already made (if any).

369. Comprehensive future Plan.

370. Benefits.
371. Bio-data of all investigators including Incharge of the Research project giving the name. qualifications with years and experience.

FORM 'B'

[See rule S (l)]

Application for grant of aid for conducting clinical trials

372. Name and address of the applicant.

373. Name and address of the sponsor if he is other than applicant.
374. Title of Research project.

375. Financial implications of the project:
376. Total Financial implications.

377. Present Investment.

378. Other sources of finance, if any.
379. Amount required from the Central Research Fund and details of its proposed utilisation. 5. Enclose herewith--

380. outline of the Research Project, its purpose, benefits, description of the comprehensive plans. and progress already made, if any :

381. information and data about the drug to be investigated including its exact composition, chemistry. pharmacology, toxicity, conditions for use in man, and pharmacy with special reference to the method of manufacture and quality control to show that adequate standards exist and a meaningful assessment can be made of the safety of the material for use in man (copies of all informational material to be supplied to the investigator should be enclosed);

382. results of pre.clinical investigation including animal studies directed towards defining its safety and efficacy; and

383. an agreement from the sponsor and the applicant that they shall notify the Federal Government and all investigators if they become aware of any adverse effect arising during the course of investigation.

Note: When an investigator himself wishes to act as sponsor conducting an investigation, the amount of information required under item 4 (ii) and (iii) may vary but should be sufficient to identify the compound under investigation together with the facts which satisfy that the substance may be justifiably administered to human beings with reasonable margin o f safety. 6. Bio-data of all investigators including Incharge of the Research project giving the name,

THE DRUGS (FEDERAL INSPECTORS, FEDERAL DRUG LABORATORY

AND FEDERAL GOVERNMENT ANALYSTS) RULES, 1976

S. R. O. 793 (1)176: In exercise of the powers conferred by Sec. 43 of the Drugs Act, 1976 (XXXI of 1976), the Federal Government is pleased to make the following rules, the same having been previously published as required by sub-section (3) of the said section, namely

1 Short title and Commencement : (I) These rules may be called 'the Drugs (Federal Inspectors, Federal Drug Laboratory and Federal Government Analysts) Rules, 1976.

(2) They shall come into force at once.

384. Definitions: In these rules, unless there is anything repugnant in the subject or context,--

(a) "Act" means the Drugs Act, 1976 (XXX1 of 1976);

(b) "Section" means a section of the Act; and

{c) "form" means a form set forth in the Schedule.

385. Qualification of Federal Inspectors: (1) A Federal Inspector shall be a person who-

386. has a degree in Pharmacy from a Pakistani University or any other institution recognised for this purpose by the Federal Government; and

387. has for a period of, or for periods: aggregating, not less than ten years' practical experience in, (i) the manufacture, testing or analysis of drugs, or (ii) in drug administration:

Provided that the condition of experience may be relaxed in exceptionally deserving cases or for persons with higher qualifications or where the candidate; with requisite experience are not readily available:

Provided further that the Federal Government may, by notification in the official Gazette, for the exercise of such powers as may be specified in such notification, appoint as ex officio Inspector any officer of medical or public health department who is a registered medical practitioner or any officer who is working in the drugs administration of a Government who has a degree in Medicine or Science or Pharmacy or any person having similar qualifications working as a teacher in any pharmaceutical or medical educational institution

388. The Federal Inspector shall be under the control of the licensing authority referred to in Section 18.

Explanation: For the purposes of this sub-rule and rule 4, "licensing authority" means the Director General Health, Government of Pakistan, or an officer authorised by him in this behalf.

389. Duties of Federal Inspectors: (1) Subject to the instructions of the licensing authority, it shall be the duty of an inspector, within the local limits for which he is. appointed--

390. to inspect not less than twice a year, all premises licensed for the manufacture of drugs including the plant and the process of manufacture, the means employed for standardising and testing the drugs,, the methods and places of storage, the location,

construction and administration of the establishment likely to affect the potency for purity of the product, records and registers and to satisfy himself that the conditions of the licence and the provisions of the Act and the rules made thereunder, are being observed ;

391. to inspect from time to time establishment licensed for the import, export or sale of drugs and to satisfy himself that the conditions of the licence are being observed;

392. to send forthwith to the licensing authority after each inspection a detailed-report indicating the conditions of the licence and provisions of the Act and the rules made thereunder which are being observed and the conditions and provisions, if any, which are not being observed;

393. to take samples of any drug w hich he has reason to suspect that it is being manufactured, stocked, sold or exhibited for sale in contravention of the provisions of the Act or the rules made thereunder. and send them for test or analysis;

394. to investigate any complaint in writing which may be made to him; [.....]

395. to institute, if necessary, prosecutions in respect of breaches of the Act and the rules made thereunder. and

396. to give advice to pharmaceutical industry on technical matters pertaining to the manufacture of drugs in accordance with good manufacturing practices with a view to improve the standard of industry and quality control of drugs;

397. to conduct surveillance of the marketed drugs for ensuring quality control and compliance of the various provisions of the Act and these rules, and

398. to assist in organizing and conducting the programme for monitoring of the adverse reactions of drugs.

399. A Federal lnspector shall, for the purpose of clause (i) of sub-section(l) of Section 18 take the approval of, and for the purpose of clause (ii) of sub-section (3) and sub-section (5) of Section 19, send the sample to, or, as the case may be, inform. the Registration Board in the case of registered Drugs and the Central Licensing Board in all other cases.

400. Form of orders not to dispose of storks: An order in writing by an Inspector under clause (i) of sub section (I) of Section 18 requiring a person not to dispose of any stock in his possession shall Form 1.

401. Form of receipt for seized drag: A receipt by an inspector for the stock of any drug seized under clause (f) of sub-section (.1) of Section 18 shall be in Form 2.

402. Form of Intimation of purpose of taking samples: Where an Inspector takes a sample of a drug for the purpose of test or analysis, he shall intimate such purpose in writing in Form 3 to the person from whom he takes it.

403. Procedure for despatch of sample to Government Analyst: (1) The portion of sample or the container sent by an Inspector to the Government Analyst for test or analysis under sub-section (3} o f Section shall be sent by registered post or by hand in a sealed packet enclosed together with a memorandum in Form 4 in an outer cover addressed to the Government Analyst.

404. A Copy of the memorandum and a specimen impression of the seal used to seal the packet shall be sent to the Government Analyst.

405. Confiscation of drugs: When any person has been convicted under the Act for contravening the provisions of clauses (a) to (e), (g) and (h) of Section 23, the stock of the drug or a substance in respect o f which the contravention has been made may be confiscated if the Drug Court so directs.

406. Prohibition of disclosure of Information: Except for the purpose of official business or when required by a Court of Law, an Inspector shall not, without the sanction in writing of his official superior, disclose to any person any information acquired by him in the course of his official duties.

407. The Federal Drug Laboratory: This Federal Drug Laboratory shall have the following functions, namely :--
(i) to test and analyse such samples of drugs as may be sent to it under sub-section (5) of Section 22;

(ii) to test or analyses such samples as may be sent to it by the Federal Government:

(iii) to carry out such other functions as may be entrusted to it by the Federal Government or, with the prior approval of the Federal Government, by & Provincial Government.

408. The Regional Drugs Testing Laboratory. The Regional Drugs Testing Laboratories established by the Federal Government shall perform the following functions, namely :--

409. to test and analyse such samples of drug as may be sent to it under sub-section (2) of Section 33;

410. to analyse such samples as may be sent to it by the Registration Board,. the Central Licensing Board or a Federal Inspector;

411. to carry out such other functions as may be entrusted to it by the Federal Government or, with the prior approval of the Federal Government, by the Provincial Government.

412. Qualifications of Federal Government Analysis: A Federal Government Analyst shall be a person who has a degree in Pharmacy or Pharmaceutical Chemistry or Medicine of a Pakistani University or of any other institution recognised by the Federal Government for this purpose and has pot less than three years post-graduate experience in the test a nd analysis of drugs or experience of the Drugs Control Administration or Drugs Quality Control Administration or of both for a period aggregating not less than five years.

413. Despatch of samples for teat or analysis: (1) Samples for test or analysis shall be sent to the officer for the time being incharge of the Federal Laboratory by registered post in a sealed packet, together with a memorandum in Form 5, in case the sample is being sent under sub-section (5) of Section 22.

414. The packet, as well as the outer cover shall be marked with a distinguishing number.

415. In the case of submission of samples under sub-section (5) of Section 22, a copy of the memorandum in Form 5 and a specimen impression of the seal used to seal the packet and a sample of the cloth and thread, if used, shall be sent to the officer for the time being incharge of the Federal Laboratory.

416. Recording of condition of seals: (1) On receipt of the packet, it shall be opened by the officer for the time being incharge of the Laboratory, a Government Analyst or any responsible officer authorised in writing by any of them in this behalf who shall record the conditions of the seals on the packet, on the form accompanying the sample, and on a register maintained for the purpose.

417. Immediately on receipt of the sample, the officer opening the packet containing the sample shall examine the sample for any contravention of provisions of the Act in respect of labelling.

418. Report of result of test or analysis: (1) After test or analysis the result thereof together with full protocols of the test applied, shall be supplied forthwith to the sender in Form 6.

419. The Government Analyst shall, for the purpose of sub-section (1) of Section 22, forward a copy of the report to the Registration Board in the case of a registered drug and to the Central Licensing Board in all other cases.

420. For the purpose of sub-section (2) of Section 22, the further period within which the report should be made available to the Inspector shall be sixty days.

421. Signature on certificate: Certificates issued under these rules by the Laboratory, or a Government Analyst shall be signed by the officer-in-charge of the Laboratory or by an officer authorised by the Federal Government by notification in the official Gazette to sign such certificates or by a Government Analyst, as the case may be.

422. Fees: The fees for test or analysis of any drug shall be those specified in Schedule II.

SCHEDULE 1
FORM 1
(See rule 5)

ORDER UNDER SECTION 18 (1) OF THE DRUGS ACT 1976, REQUIRING A PERSON NOT TO DISPOSE OF STOCK IN HIS POSSESSION.

Whereas I have reason to believe that the stock of drugs in your possession detailed below contravenes the provisions of the Drug. Act, 1976 or rules made thereunder; and whereas I

have reported the: facts to tee Board concerned or the authority and have been authorised by it to take action under clause (i) of Section 18 of the said Act;

I hereby require you not to dispose of the said stock for a period of .....days from

this date.

Date..... Inspector .....

Details of stock of drugs

Inspector .....

FORM 2

(See rule 6)

RECEIPT FOR STOCK OF DRUGS SEIZED UNDER SECTION 8 (f) OF THE DRUGS ACT, 1976

The stock of drugs/materials/articles detailed below has this day been seized by me under the provision of clause (f) of Section 19 of the Drugs Act, 1976, from the premises

of..... situated.....

Date ..... Inspector .....

Details of drugs seized

Inspector.....

FORM 3

(See rule 7)

INTIMATION TO PERSON FROM WHOM SAMPLE IS TAKEN.

I have this day taken from the premises of .....situated at

.....samples of the drugs specified below for the purposes of test or analysis.

Details of sample taken

Inspector .....

FORM 4

(See rule 8)

MEMORANDUM TO GOVERNMENT ANALYST

Serial No .....

From .....

To

The Federal Government Analyst.

The portion of sample/container described below is sent herewith for test and analysis under the provisions of clause (i) of the sub-section (3) of Section 19 of the Drugs Act, 1976.

The portion of sample or container has been marked by me with the following mark :-

Details of portion of sample or container with name of drug which it purports to contain :-

Date…… Inspector .....

FORM 5

(See rule 14)

MEMORANDUM TO THE FEDERAL LABORATORY

Serial No .....

From .....

To the Officer. in-charge, Federal Drugs Laboratory.

I send herewith, under the provisions of section .....of the Drugs Act, 1976, sample (s) of a drug purporting to be ..... for test or analysis and request that a report of the result of the test or analysis may be supplied.

2. The distinguishing number on the packet is ……

3. Particulars of offence alleged .....

4. Matter on which opinion is required.....

Date ..... Drug Court.

FORM 6

(See rule 16)

CERTIFICATE OF TEST OR ANALYSIS BY THE FEDERAL 'DRUGS LABORATORY/GOVERNMENT ANALYST

Certified that the samples, bearing number..... purporting to be a sample

of.....received on .....with memorandum No

.....Dated.....from.....has been tested/analysed and that

the result of such test/analysis is as stated below :-

423. The condition of the seals on the packet of receipt was follows .....

424. In the opinion of the undersigned the sample is not/is .adulterated/ sub standard/misbranded/spurious, as defined in the Drugs Act, 1976 for the reasons given below :-

Details of results of test or analysis: (with protocols of tests applied}.

Director, Federal Drugs Laboratory

or other authorised officer/Government Analyst.

Secretary

DRUGS (IMPORT & EXPORT) RULES, 1976

S R O. 890 (I)/76. In exercise of the powers conferred by Section 43 of the Drugs Act, 1976 (XXX! of 1976), the Federal Government is pleased to make the following rules, the same having been previously published as required by sub-section (3) of the said. section) namely :--

CHAPTER I

425. Short title and commencement. (1) These rules may be called the Drugs (import and Export) Rules, 1976.

(2) They shall come into force at once.

426. Definitions. In these rules unless there is anything repugnant in the subject or context :-

(a) "Act" means the Drugs Act, 1976 ('XXXI of 1976); and

(b) "form" means form appended to these rules.

CHAPTER 11

IMPORT OF DRUGS

427. Import of finished drugs. Finished drugs may be imported subject to the following conditions, namely :-

428. the importer possesses a licence to sell by way of retail wholesale, the drug intended to be imported and has adequate facilities for proper storage to preserve its properties

429. the importer shall, within fifteen days of establishing the letter of credit, intimate such action on Form I to an officer authorised by the Federal Government in this behalf;

430. the drug shall be imported in containers intended for retail sale or supply to hospitals, dispensaries or such other institutions; and

431. the drugs shall be imported against indents issued by the authorised indentors or local agents of the manufacturers.]

Provided that such drug may be imported in bulk containers by any person who possesses a licence for re-packing and has obtained permission in writing to such import from an officer authorised by the Federal Government in this behalf.

432. Types of licences to import drugs. Licences to import drugs shall be of the following types, namely :--

(i) licence to import drug other than the finished drugs; and

(ii) licence to Import small quantities of drugs for the purpose of clinical trial, examination, test or analysis.

433. Licences for import of drugs manufactured by one manufacturer. A single application shall be made, and a single licence shall be required, in respect of the import of more than one drug or class of drugs manufactured by the same manufacturer:

Provided that if a manufacturer front whom the drugs are to be imported has two or more premises manufacturing the same or different drugs. a separate application shall be made,. and a separate licence shall be required, in respect of the. drugs manufactured in each such premises.

434. Application for licence to import drugs. (1) An application for licence to import drugs other than finished drugs shall be made to the licensing authority in Form 2 and shall be accompanied by a fee of fifty rupees and by an undertaking in Form 3, signed by or on behalf of the manufacturer:

Provided that in the case of a subsequent application by the same importer for addition to the import licence of any drug manufactured by the same manufacturer, the fee to accompany each such application shall be twenty-five rupees.

435. A fee of twenty. five rupees shall be paid for a duplicate copy of licence issued under this Chapter if the original is defaced, damaged or lost.

436. An application for a licence to import small quantity of drugs for the purpose of clinical trial, examination, test or analysis shall be made to the licensing authority in Form 4; and the licensing authority may require such other particulars to be supplied as it may consider necessary.

437. Any fee deposited under sub rule (1) or sub rule (2) shall in no case be refunded.

438. Licence to import drugs. A licence to import drugs other than finished drugs shall be issued in Form 5 and for the import of small quantity of drugs for clinical trial, examination, test or analysis shall be issued in Form 6.

439. Duration of licence to import drugs. Licence to import drugs, unless earlier suspended or cancelled, shall be valid for two years.

440. Licensing authority. For the purpose of this Chapter, "licensing authority" means the authority appointed by the Federal Government to issue licences to import drugs and includes any person subordinate to it to whom such authority may, with the approval of the Federal Government by an o rder in writing, delegate the power to sign licences and such other powers as may be specified in the order.

441. Grant of licence to import drugs. On receipt of an application fern licence to import drugs the licensing authority shall. on being satisfied that, if granted, she conditions of the licence will be observed issue an import licence.

442. Conditions of licence to import drugs other than finished drugs: A licence to import drugs other than finished drugs shall bc subject to the following conditions, namely :--
(i) the manufacturer shall at all times observe the under-taking given by him or on his behalf in Form 3;

443. the license shall allow the licensing authority or any person authorised by it in this behalf to enter, with or without prior notice. any premises where the imported drug is stocked to inspect the means, if any, employed for testing the drug and to take samples;

444. the licensee shall on request furnish to the licensing authority from every batch of each drug or from such batch or batches as the licensing authority may from time to time specify as sample in such quantity as the licensing authority may consider adequate for any examination, test or analysis required to be made, and the license shall, if so required furnish full protocols of the tests, if any which have been applied;

445. the licensee shall ensure proper storage facilities for preserving the properties of the imported drug;

446. the licensee shall maintain a complete record of utilization of the imported drug, showing particulars of the substance manufactured from it and such further particulars, if any as the licensing authority may specify and such record shall be open to the inspection of licensing authority or any person authorised in this behalf by the licensing authority

447. the licensee shall comply with such further requirements, if any applicable to the holders of import licences, as may be specified in any rules subsequently made under the Act in this behalf and of which the licensing authority has given to him not less than three months notice.

448. Conditions of licence to import small quantities of drugs for clinical trial, etc : A licence to import small quantities of drugs including drugs the import of which is otherwise

prohibited under the Act for the purposes of clinical trial, examination, test or analysis shall be subject to the following conditions, namely:-

449. the licensee shall exclusively use the drug for the purpose for which it has been imported and at the place specified in the licence, or at such other plate as the licensing authority may from time to time authorise;

450. the licensee shall allow the licensing authority or any person authorised by it in this behalf to enter, with or without prior notice, the premises where the drugs are kept and to inspect the premises and investigate the manner in which the drugs are being used and to take samples thereof;

451. the licensee shall keep record of, and shall report to the. licensing authority, the drugs imported under the licence, together with the quantities imported, the date of importation and the name of the manufacturer;

452. the licensee shall comply with such further requirements if any, applicable to the holders of licences for clinical trial, examination, test or analysis as may be specified in any rules subsequently made under the Act and of which the licensing authority has given to him not less than .one month's notice.

453. Import of drugs for personal use: Small quantities. of drugs including drugs the import. of which is otherwise prohibited tinder the Act may be imported for personal use subject to the following conditions. namely :--

454. the drugs shall form part or a passenger's bona fide baggage and shall be intended for the exclusive .personal use. of the passenger;

455. the quantity of any single drug so imported shall not exceed one hundred average doses:

Provided that any drug imported for personal use but not forming part of bona fide personal baggage may be allowed to be imported subject to the following conditions, namely :-

456. the licensing authority on an application being made to it prior to the import, and. being satisfied that the drug is for bona tide personal use has granted permission for the import of the said drug; and

457. the quantity to be imported is, in the opinion of the licensing authority, reasonable and is covered by a prescription from a registered medical practitioner.

458. General provisions regarding import: An importer of drugs. except where such import is for personal use, shall comply with the following general provisions, namely :--

459. the importer shall allow any person authorised in. this behalf to enter, with or without prior notice, any premises where the imported drugs are stocked, to inspect the storage facilities and to take samples for testing ;

460. the importer shall, on being informed by the Registration Board or the licensing authority or an officer authorised by it in this behalf or the Chairman .of the Provincial Quality Control Board that any part of any batches of a drug has been found to be in contravention of the provisions. of the Act or the rules made thereunder and on being directed so to do, withdraw the remainder of that batch from sale and, so far as practicable, recall the issues already made from that batch and dispose of in such manner as the Board or, as the case may be, the authority, may direct;

461. the importer shall maintain a record of all sales by way of wholesale made by him of the imported drugs, and such record shall be open to the inspection by any person authorised in this behalf;

462. the importer shall ensure that the import of each batch of a drug is accompanied by--

463. a batch certificate in Form 7 from the competent health authority or any other such agency of the country of export or from the manufacturer;
464. a copy of the test report of the drug from the competent health authority or any other such agency of the country of export or from the manufacturer;

465. the importer shall maintain an inspection book on which a member of the Registration Board or of the licensing authority or an Inspector shall record proceedings of each of his visits, his impressions and the defects notified by him and such inspection book shall be signed by him as well as the. licensee or his authorised agent;

466. the importer, shall on receipt of information of arrival of the consignment of drugs at the port of importation report in Form 8 alongwith three copies of the invoice to the officer authorised by the Federal Government to grant clearance under rule 15.

467. Procedure at customs -ports: (1) No drug shall be released from the customs unless a clearance certificates has been obtained by the importer from an officer authorised in this behalf by the Federal Government.

468. If the Collector of Customs or an officer authorised by him has reason to s uspect that any drug does not comply with the provisions of the Actor the rules made thereunder, he may, or if requested by as officer authorised in this behalf by the Federal Government shall, take samples of any drugs from the consignment and forward them to the officer-in charge of the laboratory appointed for the purpose by the Federal Government and may detain the drugs from the consignment of which samples have been taken until the report of the officer-in charge of the said laboratory on such samples is received:

Provided that if the importer gives an undertaking in writing not to dispose of the drugs without the consent of the Collector of Customs and to return the consignment or such portion thereof as may be required, the Collector of Customs shall make over the consignment to the importer.

469. If an importer who has given an undertaking under the proviso to sub-rule (2} is required by the Collector of Customs to return the consignment or any portion thereof. he shall return the consignment or portion thereof within ten days of receipt of the notice.

470. If the officer-in-charge of the laboratory appointed for the-purpose by the Federal Government reports to the Collector of Customs that the samples of any drug in a consignment do not conform to the specification or that the drug contravenes in any other respect the provisions of the Act or the rules made thereunder and that the contravention is such it cannot be remedied by the importer, the Collector of Customs shall communicate the report forthwith to the importer who shall within two months of his receiving the communication, either export all the drugs of that description in the consignment to the country from which they were imported or surrender them to the Federal Government for disposal in such manner as it may deem fit:

Provided that the importer may, within fifteen days of the receipt of the report make a representation against the report to the Collector of Customs who shall forward the representation with a further sample to the licensing authority or, as the case may be, the Registration Board which after obtaining, ff necessary, the report of the .officer-in-charge of the Federal Drugs Laboratory, shall pass orders thereon which shall be final.

471. If he officer-in- charge of the laboratory appointed for the purpose by the Federal Government reports to the Collector of Customs that the samples of any drug contravene in any respect the provisions of the Act or the rules made thereunder and that the contravention is such that it can be remedied by the importer, the Collector of Customs shall communicate the report forthwith to the importer and permit him to import the drug on his giving an undertaking in writing not to dispose of that drug without remedying the said contravention.

472. A Federal a provincial Inspector Inspector or a person authorised in this behalf by the Federal Government may physically inspect the consignment and draw samples from each batch for test and analysis as may be necessary and, if the consignment has been released b y the customs, may order the importer not to sell or offer for sale or dispose of the drug for a reasonable period not exceeding one month with a view to obtain a test report:

Provided that the Federal a provincial Inspector Inspector or such authorised officer may prohibit the disposal of a drug for a longer. period if he has sufficient reason to believe that the import, in any way, is in contravention of any or the provision of the Act or these rules in which case. the importer shall not dispose of that d rug until a certificate authorising the sale of the batch has been issued to him.

473. Suspension and cancellation of licence to import drugs: If the manufacturer or licensee fails to comply with any of the conditions of a licence to import drugs or violates any of the provisions of the Act or the rules made thereunder, the licensing authority may, after giving the licensee an opportunity of being heard, by an order in writing stating the reason therefor, suspend or cancel the licence for such period as it thinks tit or cancel for all times. either wholly or in respect of some of the drugs. to which it relates or, if the nature of offence is so serious that it is likely to endanger the public health, .may prohibit the import of all other drugs of the said manufacturer:

Provided that a person who is aggrieved by the suspension or cancellation of his licence, may.

within sixty days of the receipt of such order, appeal to the Appellate Board.

CHAPTER III

EXPORT OF DRUGS

474. xport of finished drugs: Finished drugs may be exported subject to the condition that the exporter possesses a licence to manufacture or sell by way of retail sale or wholesale.

475. Licences for export drugs: A licence to export drugs shall be required in Form 9 for the export of drugs other than the finished drugs.

476. Licences for export of drugs manufactured by one manufacturer: A Single application shall be made, and a single licence shall be required in respect of the export of more than one drugs or class of drugs manufactured by the same manufacturer:
Provided that if a manufacturer has two or more premises manufacturing the same or different drugs, a separate application shall be made, and a separate licence shall bc required, in respect of the drugs manufactured in each such premises.

477. Application for licence to export drugs: (1) An application for licence to export drugs shall be made to the licensing authority in Form 10 alongwith an undertaking on Form 11 signed by the manufacturer and shall be accompanied by a fee of fifty rupees:

Provided that in the case of a subsequent application by the same exporter for addition to the export licence of any drug manufactured by the same manufacturer, the fee to accompany each such application shall be twenty-five rupees.

478. A fee of twenty-five rupees shall be paid for a duplicate copy of licence issued under this Chapter if the original is defaced, damaged or lost.

479. An application for a licence to export small quantity of drugs, including drugs the export of which is otherwise prohibited u nder the Act, for the purpose of clinical trial, examination, teat or analysis shall be made to the licensing authority in Form 12; and the licensing authority may require such other particulars to be supplied as it may consider necessary.

480. Any fee deposited under sub-rule (I) or sub-rule (2) shall in no case be refunded.

481. Duration of a licence to export drugs: A licence to export drugs, unless earlier suspended or cancelled, shall be valid for two years:

Provided that if application for a fresh licence, is made three month, before the expiry of the existing licence, the current licence shall continue to be in force until orders are passed on the application

482. Licensing Authority: For the purpose of this Chapter. "licensing authority" means the authority appointed by the Federal Government to issue export licences and includes any person subordinate to it to with such authority may, with the approval of the Federal Government by an order in writing, delegate the power to sign licences and such other p owers as may be prescribed in the order.

483. Grant of export licence: On receipt of on application for an export licence, the licensing authority shall, on being satisfied that, if granted, the conditions of the licences will be observed, issue an export licence.

484. Conditions of licence to export drugs: A licence to export drugs other than finished drugs shall be subject to the following conditions, namely :-

485. the licensee shall allow any person authorised by the licensing authority in this behalf to enter, with or without prior notice, any premises where the drug to be exported is stocked to inspect the means, if any employed for testing the drug and to take samples;

486. the licensee shall on request furnish to the licensing authority from every batch of each drug or from such batch or batches as the licensing authority may from time to time specify samples in such quantity as the licensing authority may consider adequate for any examination, test or analysis required to be made and the licensee shall, if so required furnish full protocols of the tests, if any, which have been applied;

487. if the licensing authority so directs, the licensee shall not export or offer for export any batch in respect of which a sample is, or protocols are, furnished under clause (ii) until a certificate authorising the export of the batch has been issued to him by or on behalf of the licensing authority:

488. the licensee shall, on being informed by the licensing authority that any part of any batch of a drug has been found by the licensing authority not to conform to the required specifications and on being directed so to do, withdraw the remainder of that batch from export and, so far as may, in the particular circumstances of the case, be practicable, recall the issues already made from that batch;

489. the licensee shall maintain a record of all exports made by him of each drug showing particulars of the drug and of the person to whom exported and such further particulars, if any, as the licensing authority may specify, and such record shall be open to the inspection of any inspector authorised in that behalf by the licensing authority and such records shall be preserved for three years from the date of the export of the drug;

490. the licensee shall cause the drugs to be packed and labelled in conformity with the requirements of the consignee;

491. the licensee shall ensure proper storage facilities for preserving the properties of the drugs to be exported during storage;

492. the licensee shall comply with such further requirements, if any, applicable to the holders of export licenses, as may be specified in any rules subsequently made under the Act in this behalf and of which the licensing authority has given to him not less than three months' notice.

493. Export of drugs for the purposes of clinical trial, examination, test analysis or personal use: Small quantities of drugs, including drugs the export of which is otherwise prohibited under the Act, may be exported for the purposes of clinical trial examination, test, analysis or personal use with the written permission of the licensing authority.

494. Statement to accompany drugs for export: All consignments of drugs sought to be exported shall be accompanied by an invoice or other statement showing the name and address of the manufacturer and the names and quantities of the drugs.

495. General provisions regarding export: An exporter of drugs, except where such export is for personal use, shall comply with the following general provisions, namely:-

496. The exporter shall allow any person authorised in this behalf to enter with or without prior notice, any premises where the drugs to be exported are stocked, in inspect the storage facilities and take samples for testing.

497. The exporter shall, on being informed by the Registration Board or the licensing authority or an officer authorised by it in this behalf or the Chairman of the Provincial Quality Control board that any part of any batch of a drug has been found in contravention of any of the provisions of the Act or the rules made thereunder and on being directed so to do, withdraw the remainder of that batch from export and so far as practicable, recall the issues already

made from that batch and dispose of it in such manner as the Board, or, as the case may be, the licensing authority, may direct.

498. The exporter shall maintain a record of all exports of drugs made by him and such record shall be open to inspection by any person authorised in this behalf.

499. the exporter shall maintain an inspection book on which a me mber of the Registration board or the licensing authority or an Inspector shall record proceedings of each of his visits, his impressions, and the defects noticed by him and such inspection book shall be signed by him as well as the licensee or his authorised agent.

500. Procedure at customs port: (1) If the Collector of Customs or an officer authorised by him has reason to suspect that any drug does not comply with the provisions of the Act or the rules make thereunder, he may, and if requested by an officer appointed for this purpose by the Federal Government shall, take samples of any drugs from the consignment and forward them to the officer-in-charge of the laboratory appointed for the purpose by the Federal Government and may detain the drugs from the consignment of which samples have been taken until the report of the officer-in-charge of the said laboratory on such samples is received:

Provided that if the exporter gives an undertaking in writing not to export or dispose of the drugs without the consent of the Collector of Customs and to return the consignment or such portion thereof as may be required, the Collector of Customs shall make over the consignment to the exporter.

501. If an exporter who has given an undertaking under the proviso to sub-rule (I) is required by the Collector of Customs to return the consignment or any portion thereof, he shall return the consignment or portion thereof within ten days of the receipt of the notice.

502. If the officer in-charge of the laboratory appointed for the purpose by the Federal Government reports to the Collector of Customs that the samples of any dug in a consignment do not conform to the specifications or that the drug contravenes in any other respect the provisions of the Act or the rules made thereunder and that the contravention is such that it cannot be remedied by the exporter, the Collector of Customs shall communicate the report forthwith to the exporter who shall cause them to be destroyed or surrender them to the Federal Government for disposal in such manner as it may deem fit:

Provided that the exporter may, within fifteen days of the receipt of the report, make a representation against the report to the Collector of Customs who shall forward the representation with a further sample to the licensing authority or, as the case may be, the Registration Board which after obtaining, if necessary, the report of the officer-in-charge of the Federal Drugs Laboratory, shall pass orders thereon which shall be final.

503. If the officer-in-charge of the laboratory appointed for the purpose by the Federal Government reports to the Collector of Customs that the samples of any drug contravene in any respect the provisions of the Act or the rules made thereunder and that the contravention is such that it can be remedied by the exporter, the Collector of Customs shall communicate the report forthwith to the exporter and permit him to withdraw the drug on his giving an undertaking in writing not to export that drug without remedying the said contravention.

504. Suspension and cancellation of license to export drugs: If the manufacturer or licensee fails to comply with any of the conditions of license to export drugs or violates any of the provisions of the Act or the rules made thereunder, the licensing authority may, after giving the licensee an opportunity of being heard, by an order in writing stating the reasons therefor, suspend or cancel it for such period as it thinks fit or cancel for all times, either wholly or in respect of some of the drugs, to which it relates or, if the nature of offense is so serious that it

is likely to endanger the public health, may prohibit the export of all other drugs of the said manufacturer:

Provided that a person who is aggrieved by the suspension or cancellation of his license, may within sixty days of the receipt of such order, appeal to the Appellate Board.

FORM 1

[See rule 3 (ii)]

INTIMATION REGARDING IMPORT

I/We.....of.....have established the letter of credit to

conduct import of drug(s) details of which are as follows:--

505. Name of the drug(s) ----------

506. Drug Registration number(s) ----------
507. Name and address of Manufacturer ----------

508. Name and address of exporter ----------
509. Date of establishing L/C ----------

510. Quantity to be imported ----------
511. Rate per unit ----------

512. Total C & F value ----------

(xi) Mode of shipment ----------

513. Expected date of arrival ----------

514. Nature of Drugs Sale License ----------
Date---------- Signed----------

FORM 2
[See rule 6 (1)]

APPLICATION FOR LICENSE TO IMPORT DRUG(S)
I/We ----------hereby apply for import of drug(s) specified below manufactured

by---------- of----------.

NAME OF DRUG(S)
I/We----------enclose herewith an undertaking in Form 3 signed by or on behalf

of the manufacturer as required by the rule under the Drugs Act, 1976.
FORM 3

[See rule 5 (1)]
FORM OF UNDERTAKING TO ACCOMPANY AN APPLICATION FOR LICENSE TO IMPORT DRUGS
Whereas----------of----------intends to apply for a license under the Drugs

(Import and Export) Rules, 1976, for the import into Pakistan of the drug(s) specified below

manufactured by us. We----------of----------hereby give
this undertaking that:
515. the said applicant has made a contract with us for import of drug(s) mentioned in the undertaking;

516. we declare that we are bonafide licensed manufacturer of the drugs covered under this undertaking at the premises specified below and we shall report change, if any, in the said premises;
517. we shall comply with the conditions imposed on a license by the rules under the Drugs Act, 1976 and such other requirements as may the laid down by the Government of Pakistan in this behalf;

518. the drug(s) mentioned below conform(s) to the provisions or the Drugs Act, 1976, and the rules made thereunder.

NAME OF THE DRUG(S)
Particulars of the premises where manufacture is carried on.

Date---------- Signature of Manufacturer----------

FORM 4
[See rule 6 (3)]

APPLICATION FOR LICENSE TO IMPORT DRUGS FOR THE PURPOSE OF CLINICAL TRIAL, EXAMINATION, TEST OR ANALYSIS

I/We----------of----------by occupation----------hereby apply for

a license to import the drug(s) analysis at----------and I/We undertake to comply with

the conditions applicable to the license under rule 12 of the Drugs (Import and Export) Rules,

1976.

Name of drug(s)---------- Quantities----------

Manufactured by----------

Date---------- Signature----------

Name and address of applicant

FORM 5

(See rule 7)

LICENSE TO IMPORT DRUG(S)

Number of license----------M/s---------- of----------is/are hereby

licensed to import into Pakistan during the period for which this license is in force the drug(s) specified below, manufactured by----------of----------.

519. This license is subject to the conditions prescribed in the Drugs Act, 1976 and shall be in force for a period of two years from the date stated below unless it is sooner suspended or cancelled under the said Rules:

Name of Drug(s) to which this license applied:

(1) ----------

(2) ----------

(3) ----------

Date---------- Licensing Authority----------

FORM 6

[See rule 7]

LICENSE TO IMPORT DRUG(S) FOR CLINICAL TRIAL, EXAMINATION, TEST OR ANALYSIS

No. of license----------M/s----------of---------- is/are hereby licensed to import from----------the drug(s) specified below for the purpose of clinical trial, examination test or analysis at----------or in such other place as the licensing authority may from time to time authorise.

520. This license is subject to the condition prescribed in rule 12 of the Drugs (Import and Export) Rules, 1976, and such other conditions as may be prescribed by the Federal Government in this behalf.

521. This license shall, unless, previously suspended or cancelled, be in force for a period of two years from the date specified below:
Name(s) of drug(s) with quantities which may be imported

Date---------- Licensing Authority----------

FORM 7

[See rule 14 (d) (I)]

BATCH CERTIFICATION

Name and Registration No. of drug ----------

Batch number of drug ----------

Name and address of the Manufacturer ----------

Date of Manufacture ----------

Date of expiry, if any ----------

It is hereby certified that the above -mentioned drug (s) has/have been manufactured and labelled in conformity with the provisions of the Drugs Act, 1976, and the rules made thereunder.

It is further certified that this/these drug (s) has/have been manufactured under a valid permit/license issued by the competent Health or any other authority to manufacture this/these drug(s).

Signed ----------

Name, designation and official seal of the Signatory ----------

Place and date ----------

FORM 8

[See rule 14 (f)]

Intimation of arrival of consignment (s) of imported drug (s) other than those imported for personal use.

Name and address of importer.

Status (whether commercial importer or industrial consumer).

Drugs Manufacturing License No (in case of industrial consumer).

Drug Import License No. (in case of industrial consumer).

C.C.I., &E License No. with date and value of the License.

Import Policy Order applicable.

Name and address of exporter/manufacturer.

Name of drug (with dosage form for finished drug) Drug Registration No. finished drug Rate (for C & F/F.O.B.) Packing Quantity Total Value

FORM 9

(See rule 18)

LICENCE TO EXPORT DRUG (S)

Number of licence.....M/s.....of.....is/are hereby

licensed to export during the period for which this licence is in force the drug specified below

manufactured.....

522. This licence is subject to the conditions prescribed in the rules under the Drugs Act, 1976, and shall be in force for a period of two years from the date stated below unless it is sooner suspended or cancelled under the said rules.

Name (s) of drug (s) to which the licence applied:

Dated..... Licensing Authority

FORM 10

[See rule 20 (1)]

APPLICATION FOR A LICENCE TO EXPORT DRUG

I/We ..... of ..... hereby apply for licence to export the drugs specified below manufactured by.....

Name (s) of drugs

I/We .....enclose herewith an undertaking in form 11 signed by the

manufacturer/exporter as required by rule under Drugs Act, 1976.

Date ..... Exporter .....

FORM 11

See rule 20 (2)]

FORM OF UNDERTAKING TO ACCOMPANY AN APPLICATION FOR AN EXPORT LICENCE

Whereas .....of .....intends to apply for licence under the Drugs

(Import and Export) Rules, 1976 for the export of the drug (s) specified below manufactured

by .....

523. the said applicant has made a contract with use for thc purchase of drug (s) mentioned in the undertaking;

524. we shall comply with the conditions imposed on a licensee made the Drugs Act, 1976;

525. we declare that we arc carrying on the manufacture of drug (s) mentioned in this undertaking at the premises specified below and we shall from time to time, report any change of premises on which the manufacture will be carried on and, in cases where manufacture is carried on in more than one factory, any change in the distributions between the factories;

526. every drug manufactured by us for export under licence shall conform with the provisions of the Drugs Act, 1976 and the Rules made thereunder;

527. we shall comply with such further requirements if any, as may be specified by rules made by the Federal Government under the Act and of which the licensing authority has given to the licensee not less than three months notice.

List of drug (s)

Particulars of premises where manufacture is carried on.

Date ..... Signed by the manufacturer.

FORM 12

[See rule 20 (3)]

APPLICATION FOR EXPORT OF SMALL QUANTITIES OF DRUG (s) FOR THE PURPOSE OF CLINICAL TRIALS, EXAMINATION, TEST OR ANALYSIS OR FOR PERSONAL USE

l/We ..... of ..... hereby apply for permission to export the drug (s) specified below

manufactured by of ..... for the purpose of ..... clinical trials, examination, test

or 2analysis or for personal use

Name (s) of drug (s)

Date..... Exporter .....

Drugs (Specifications) Rules, 1978

Notification S.R.O. 1080 (1)/78: In exercise of the powers conferred by Section 43 of the Drugs Act, 1976 (XXXI of 1976), the Federal Govern moist is pleased to make the following rules, the same having been previously published as required by sub-section (3) of the said section, .namely :--

528. Short title and commencement: (1) These rules may bc called the Drugs (Specifications) Rules, 1978.

(2) They shall come into force at once.

529. Specifications: The specifications for the classes of drugs specified in column 1 of the schedule shall be those specified against those drugs in column 2 of the schedule.
SCHEDULE
Specifications for Drugs

SCHEDULE

Specifications for Drugs

Class of drug	Specifications to be compiled with
530. Drugs bearing reference on the lebelling to any of the publications specified under sub-clause t (ii) of clause (z) of Section 3.	Specifications given in the publication referred to on the labelling.
531. Drugs included in the recent editions of any of the following publications but not bearing any reference to such publication :- (a) the international Pharmacopoeia or such other specifications as published by the World Health Organisation,	Specifications as approved by the Registration Board for this purpose and if no such approval is available the specifications given in the said publications in the same order of preference as given in column 1.
(b) the European Pharmacopoeia,	
(c) the United States Pharmacopoeia,	
(d) the British Pharmacopoeia,	
(e) the British Pharmaceutical Codex.	
(f) the United States .National Formulary.	Specifications as approved by the Registration
532. Veterinary drugs	

	Board for this purpose and if no such approval is available, the specification given in the current edition of British Veterinary Codex and, if a drug is not included in the current edition and is included in an earlier edition the specification proscribed in that edition.
533. Drugs other than those falling under serial number 1, 2 or 3 above.	Specifications as approved by the Registration Board for specification are available the ingredients and their quantities displayed in the labelling which shall be tested and analysed by the Government Analyst or the Federal Drug Laboratory or such other laboratory as may have been specified to be the laboratory for the purpose of sub-section (5) of section 22.
	In addition to the requirements, if any, set out above, ophthalmic preparations shall meet the following requirement:-
	A-Ophthalmic Solutions and Suspensions; Ophthalmic solutions and suspensions shall--
5. Ophthalmic preparations	534. be sterile except in case of those ophthalmic solutions and suspensions which are not specifically required to comply with the test for 'Sterility' in the Pharmacopocia;
	535. contain one or more suitable substances as preservatives to prevent the growth of micro-organisms Provided that solutions in used surgery shall not have any preservative and be packed in single dose containers;
	(c). be free from foreign matter:
	536. be contained in bottles made of either neutral glass or soda glass specially treated to reduce the amount of alkali released when in contact with aqueous liquids or in suitable plastic containers which would not in any way be incompatible with the solution and the droppers to be supplied with the containers shall be made of neutral glass

or of suitable plastic material and when supplied separately shall be packed in sterile cellophane or other suitable packings; and

B-- Ophthalmic Ointment Ophthalmic Ointment shall--

537. be sterile;

538. be free from foreign matter

NOTIFICATION

Islamabad, the 27th October, 1996

S.R.O. 1214(I)/96.- In exercise of the powers conferred by sub-section (1) of section 44 of the Drugs Act, 1975 (XXXI of 1976), the Chief Executive, Northern Areas is pleased to make the following Drugs Rules, namely:-

The Northern Areas Drugs Rules, 1996.

PART I.-PRELIMINARY

539. Short title and commencement.- (1) These rules may be called the Northern Areas Drugs Rules, 1996.
(2) They shall come into force at once.

540. Definitions.- In these rules, unless there is anything repugnant in the subject or context:-

(a) "Act" means the Drugs Act, 1976 (XXXI of 1976);

(b) "Board" means the Northern Areas Quality Control Board;

(c) "Form" means form prescribed in Schedule "A".

(d) "Government" means the Kashmir Affairs and Northern Affairs Division and Northern Areas Administration;

(e) "Narcotic and other controlled drugs" means the drug specified in Schedule "B".

(f) "Pharmacy" means a shop, store or place where drugs are compounded or prepared on prescription, it shall include a place which bears the words. Pharmacy, Pharmacist or dispensing chemist and shall conform to requirement laid down in Schedule "F".

(g) "Registered Medical Practitioner" means a medical practitioner registered under the Pakistan Medical and Dental Council Ordinance, 1962 (XXXII of 1962);

(h) "Schedule" means a schedule to these rules;

(i) "section" means section of the Act; and

(j) "Whole Sales" sale by way of whole sale dealing, means, sale to a person who buys for the purpose of selling again.

PART II.-NORTHERN AREAS QUALITY CONTROL BOARD GOVERNMENT ANALYST AND DRUG INSPECTOR.

541. Northern Areas Quality Control Board.-

542. The Board shall consist of the following members, namely:-

(a) Director Health Services, Northern Areas, Gilgit Chairman

(b) Medical Superintendent, District Health Officer, Hospital Gilgit Member

(c) Deputy Commissioner, Gilgit Member

(d) Drug Inspector, Directorate of Health Services Norther Areas, Gilgit. Secretary

543. The Board may co-opt any other qualified expert having formal training and experience in the Pharmaceutical field.

544. The quorum to constitute a meeting of the Board shall be three including its Chairman.

545. No act or proceeding of the Board shall be invalid merely on the ground of the existence of any vacancy in or any defect in the constitution of the Board.

546. Functions of the Board.-(1) The Inspector and the Government Analyst shall submit monthly returns in Form-1 and Form-2 respectively, to the Board and a summary on the over all situation of quality control in the area under their respective jurisdiction and the Board shall maintain such information so as to monitor the quality of all the drugs sold and to keep watch on the performance of all manufacturers and the drugs sale licence holder.

547. The Board shall, as far as possible, meet at least once in a month and review the situation of the quality control of drugs on whole including consideration of any specific point arising during the period on the working of various Firms. Drug Testing Laboratories and Inspectors.

(3). The Board shall examine the cases referred to it by any Inspector under the Act before directing him to prosecute such accused or recommending to the Licensing Authority for cancellation or suspension of the licence, provided that no such action shall be taken without a show cause notice to the accused.

548. Before referring any case to the Drug Court, the Board shall ascertain the name of the Directors, Partners and e mployees of the Company, Corporation, Firms or institutions who are

prima facie responsible for the commission of the offence under the Act or the rules and allow an Inspector to institute prosecution only against such persons.

549. The Board may in view of minor contravention of offences in its discretion, advise the accused to make improvement, or if considered necessary, issue a warning to the accused.

550. Qualifications of Inspectors and Analyst.- (1) No person shall be appointed as a Inspector unless he posses a Degree in Pharmacy from a Pakistani University or any other Institution recognised for this purpose by the Pharmacy Council of Pakistan and has at least one year experience in the manufacture, retail sale testing or analysis of drug or in the Drug Control Administration or in a Hospital Pharmacy:

Provided that for dealing with specific cases, the Government may appoint as ex-officio inspector any Gazetted Officer of Medical or Public Health Department, who is a Registered Medical Practitioner, or any officer working in the Health Administration, who has a degree in medicine or pharmacy or any other person having similar qualification and is working as a teacher in Pharmacy or Medical Education:

Provided further that the ex-officio Inspector shall be appointed for the purpose of conducting inspection of:-

551. any premises wherein any drug is sold or is stocked or exhibited for sale or distribution;

552. the storage arrangements and all relevant records registers; and

553. taking samples of any drug which is being sold or is stocked or exhibited for sale or is being distributed.

554. No person shall be appointed as an Analyst unless he possesses a Degree in Pharmacy from a Pakistani University or any other Institution recognized for this purpose by the Pharmacy Council of Pakistan and has at least five years experience preferably in the manufacture, testing or analysis of drugs or in the Drugs Control Administration;

Provided that the provisions of these rules shall not apply to the Analysts who were appointed as such on regular basis before the coming into force of these rules.

555. Duties of Drug Inspector.- Subject to the instructions of the Licensing Authority, it shall be the duty of Drug Inspector:-

556. to inspect not less than twice a year all establishments of drugs licenced for sale and all establishments licenced for manufacture of drugs within the area assigned to him and to keep record of such inspections;

557. to satisfy himself that the conditions of the licences are being observed;

558. to take and send for test or analysis if necessary, samples of any drug which he has reason to suspect is being manufactured, sold, stocked or exhibited for sale in contravention of any of the provisions of the act;

559. to investigate any complaint in writing which may be made to him and furnish the report in respect thereof to the Licensing Authority;

560. to institute prosecution in respect of contravention of the Act and these rules; and

561. to maintain record of all inspections made and actions taken by him in the performance of his duties, including the taking of samples and seizure of stocks, and submit report of such record as may be required by the Quality Control Board.

562. Prohibition of Disclosure of Information.- Except for the purpose of official business or when required by the Court of Law, an Inspector or any Analyst shall not disclose to any unauthorised person any information acquired, by him in the course of his official duties.

563. Form of order not to dispose off stock.- An order in writing by an Inspector under clause (I) of sub-section (1) of section 18 of the Act, requiring a person not to dispose of any stock in his possession shall be in Form-3.

564. Form of intimation for the purpose of taking samples.- (1) Where an Inspector takes a sample of drugs under clause (c) of sub-section (1) of section-18 of the Act, for the purpose of test or analysis, he shall intimate such purpose in writing in Form-4, to the person

from whom he takes it and where he seizes stock of drug or other material under clause (f) of section 18 of the Act, the receipt for such drugs and material shall be in Form-5.

565. The Inspector shall send a portion of the sample or the container to the Analyst for test and analysis under clause (I) of sub-section (3) of section 19 of the Act, through a memorandum in Form-6.

566. The Inspector shall send a specimen impression of his seal to the Analyst and shall inform him of any change.

567. Powers to transfer cases.- Where an offence is found to have been committed in an area outside the jurisdiction of an Inspector, he shall transfer the case with all details and material to the concerned Inspector for conducting investigation and prosecution as may be considered necessary.

568. Duties of Government Analyst.- (1) An Analyst shall cause to be analysed or tested such samples of drugs as may be sent to him under the Act and shall furnish report, the result of test and analysis on Form-7, in accordance with these rules.

569. An Analyst shall cause to be tested and analysed such samples of drugs as may be sent to him in writing from a Government Department or any other public institution and shall furnish the report of the result of test and analysts to the Government Department or the public institution concerned.

570. An Analyst shall forward monthly report giving results of samples tested and analysed during the period under report for publication at the discretion of the Federal Government and furnish such other information as may be required by that Government.

571. Procedure on receipt of samples from Inspector.- On receipt of a package from an Inspector containing a sample for test and analysis, the Analyst shall compare the seals on the packet with the specimen impression received separately and shall note the condition of the seal on the package and after the test or analysis has been completed, he shall forwith supply to the Inspector a report of the result of the test and analysis.

572. Fee for test and analysis of drugs.- The fee for test and analysis of drugs in respect of samples sent by a person other than an Inspector or a Government Institution shall be determined by the Government Analyst or the person Incharge of the Government Laboratory in accordance with the fees specified in Schedule "C".

PART III.-SALES OF DRUGS

573. Licensing Authority.- (1) The Chief Inspector of Drugs or Secretary Quality Control Board will be the drugs licensing authority for all type of drug sale licence within the area of his jurisdiction.

574. Type of Licences to sell Drugs.- The licences under these rules shall be of the following types, namely:-

575. licence for drugs by way of retails sale;

576. licence for drugs by way of whole sale;

577. licence for narcotics and other controlled drug; and

578. licence for drug in a Pharmacy.

579. Application for licence to sell Drug and fees thereof.- (1) Application for the grant or renewal of a licence referred to in clause (I) to (iv) of rule 15 shall be made in Form-8, to the licensing authority. The fee shall be charged as under:-

580. one thousand rupees for the grant of a licence to sell either the drugs specified in the clause (I) to (iv) of rules 15; and

581. five hundred rupees in case of renewal of such licence subject to the condition that the provisions of these rules have been complied with.

582. A fee of five hundred rupees shall be paid for a change of a qualified person and a duplicate copy of the licence referred to in clause (I) to (iv) of rule 15, if the original is defaced, damaged or lost and such copy of the licence shall bear the words "duplicate copy."

583. The fees so collected will be utilised as under:-

584. fifty per cent of the fee shall be deposited into Government Treasury under the relevant Head of Accounts; and

585. remaining fifty per cent of the fee shall be utilised on day to day expenses for collection of samples, packing and parceling of the samples to the Government Testing Laboratories, besides other petty expenditure in the Chief Drug. Inspectors office, proper Accounts of the same will be maintained accordingly.

586. Forms of Licences to sell Drugs.-(1) A licence to sell, store exhibit for sale or distribute drugs by way of retail sale shall be issued in Form-9.

587. A licence to sell, store exhibit for sale or distribute drugs by way of whole sale shall be issued in Form-10.

(3). A licence to sell, store, exhibit for sale or distribute narcotics, and other controlled drugs shall be in Form-II.

(4). A licence to sell drugs in a Pharmacy shall be in Form-12.

588. Sale at more than one place.- If drugs are sold, stored, exhibited for sale or distributed or more than one place, a separate licence shall be required in respect of each such place.

589. Duration of licences.- (1) A licence issued under these rules shall unless suspended or cancelled earlier, remain in force for two years -from the date of issue, and if an application for renewal of such licence is not made within one month of its expiry of the licence shall stand cancelled.

Provided that if an application for renewal of a licence is made before the expiry of the period of its validity or where it is not done so far, reasons beyond the control of the licence and the application is made within one month of the expiry of the licence shall continue to be in force, until orders are passed on the application.

590. An application for renewal shall be disposed of within three months of the receipt of such application after receiving inspection report from the Inspector concerned.

591. Pre-conditions for the issue of licence.- (1) The licensing Authority shall not issue:-

(a) Licences in Form-9 and Form-12, unless;-

592. the premises have proper and adequate facilities for storage of drugs and for their protection from direct sunlight, dust or dirt including refrigeration facilities;

593. the premises are-clean and in hygienic and tidy condition; and

594. in the case of Pharmacy, the requirements laid down in Schedule "F" are complied with.

595. Licences in Form-10 unless the appoint is an indentor, importer, manufacturer or distributor of drugs and fulfills the conditions laid down in sub-clause (a); and

596. licence in Form-II, unless:-

597. the applicant posses a licence in Form-9, Form-10 or Form-12; and

598. the applicant has never been convicted of any offence under the Act.

599. The sale of drugs in Forms 9, 10, 11 and 12 shall be supervised by a persons who is

registered under clause (a) and (b) of sub-section (1) of section 24 of the Pharmacy Act, 1967 (XI of 1967).

(3). In the case of renewal of already licenced premises, the licence shall not be renewed unless they employ on wholetime basis a qualified person as mentioned in sub-rule (2).

600. Conditions of licences.- (1) Licences in Forms 9, 10, 11 and 12 shall be issued subject to the conditions stated therein and to the following general conditions, namely:-

601. the supply by way of retail sale of any drug shall be recorded suitably and such records, bills or counterfoils shall be preserved for a period of at least three years from the date of such sale, and

602. drugs specified in Schedule "B" and "D" and preparations containing such drugs shall not be sold by retail sale, except on, and in accordance, with the prescription of a registered medical practitioner with the Pakistan Medical and Dental Council. A prescription shall be dispensed only once, unless or otherwise specifically directed by the prescriber to repeat it:

Provided that no such prescription shall be required for sale of these drugs to a registered medical practitioner, hospital, dispensary or any other institution approved by an order of the Licensing Authority for such sale.

603. The sale of any drug specified in Schedule "B" and "D" by way of retail sale shall be recorded at the time of supply in a register specially maintained for the purpose and the serial number of the entry in the register shall be entered in the prescription, and the following particulars shall be entered in the register, namely:-

604. serial number.

605. date of sale.

606. name of the prescriber.

607. name of the patient or purchaser.

608. name of the drug.

609. name of the manufacturer.

610. quantity.

611. batch No.

612. signature of the qualified person;

Provided that if the drugs-specified in Schedule "D" is sold on a prescription on which the drug has been sold on a previous occasion, it shall be sufficient if the entry in the register includes serial number, the date of sale, the quantity sold and a sufficient reference to an entry in the register recording the dispensing of the drug on a previous occasion.

(2) For the purpose of this rule, a prescription shall:-

613. be in writing and signed by the person giving it with his usual signature and be dated by him;

614. specify the name and address of the person for whose treatment it is given; and

615. indicate the total quantities of drugs to be supplied and the doses to be taken.

616. All invoices and bills of purchase of drugs shall be reserved for a period of at least three years.

617. In case of sale of drugs by way of whole sale by manufacturer of their authorised dealers, they must invariably ensure that the purchaser holds a valid Drug Sale Licence, and shall issue an invoice and warranty at the time of sale of drug;

618. The whole seller while selling drugs to a retailer must also invariably ensure that the retailer holds a valid Drug Sale Licence as required under the Act and these rules and shall issue an invoice and warranty at the time of sale of drugs.

(6). The invoice and warranty must bear the full name and address of the purchaser and shall be signed by the warrantor clearly indicating his name and must be dated.

619. Records shall be maintained of all purchases and sale of drugs by way of whole sale and such records shall be preserved for three years and shall include the following particulars, namely:-

620. the date of purchase and sale;

621. The name and address of the concern from which purchased and the concerns to whom sold;

622. the name of the drugs, their batch number, their dates of expiry where applicable and the quantities; and

623. the name of the manufacturer.

624. Except as otherwise provided in these rules, all registers and records maintained under these rules shall be preserved for a period of not less than five years from the date of last entry.

625. The licence shall produce for inspection on demand by an Inspector all registers and records maintained under these rules, and shall supply to the Inspector such information as he may require.

626. Substances specified in Schedule 'E' and falling under the list of poisons and those specified in Schedule 'B' shall be stored in the retail shop:-

627. in a part of premises to which customers do not have access; or

628. in an almarah, cupboard or drawer locked and reserved solely for the storage of such drugs.

629. Substance falling under the list of poisons in Schedule 'E' shall be stored in containers, impervious to the poison, and sufficient stout to prevent leakage arising from the ordinary risks of handling and transport.

630. A substance falling in the list of poisons under Schedule 'E' when compounded and dispensed, shall be labelled with the word "Poison."

631. Cancellation and suspension of licences.- (1) The Licensing Authority may, on the report an Inspector or the Board, after giving the licencee an opportunity to show cause by an order in writing stating the reasons therefore, cancel a licence issued under these rules or suspend it for such period as it thinks fit, if in its opinion the licencee has failed to comply with any of the conditions of the licence or with any of the provisions of the Act or these rules.

632. A licensee whose licence has been cancelled or suspended may appeal to the Appellate Board within sixty days of the date of such order.

[No. 10/5/96-NA.I.]

10.4 ANNEXURE-04 – BIDDING DOCUMENT WORLD BANK

Procurement of Goods or Works

The World Bank April 1996

Preface

This Standard Bid Evaluation Form has been prepared by the World Bank[1] for use by its Borrowers and their implementing agencies in the evaluation of bids, in accordance with the provisions of the Bank's *Guidelines: Procurement under IBRD Loans and IDA Credits*, January 1995, revised January and August 1996 and September 1997, referred to hereafter as ―Guidelines‖ (see in particular para. 2.53 and Appendix 1, subparas. 2 and 4 of the *Guidelines*). All loans and credits negotiated after March 15, 1995 are governed by the 1995 edition.

This document is intended specifically for assisting in the evaluation of bids procured through International Competitive Bidding (ICB), as well as through Limited International Bidding (LIB), whether subject to prior or post review. It should also prove useful, with appropriate modifications, to Borrowers for evaluation under National Competitive Bidding (NCB) procedures.

Upon notification of contract award to the successful bidder by the Borrower, and in accordance with the General Conditions of the Loan or Credit Agreement, the Bank is authorized to publish a description of the contract, the name and nationality of the contract awardee, and the contract price.

All users are invited to submit comments on their experience with this document to:

Procurement Policy and Services Group
Operational Core Services Network
The World Bank
1818 H Street, N.W.
Washington, D.C. 20433
U.S.A.
pdocuments@worldbank.org
http://www.worldbank.org/html/opr/procure/contents.html
facsimile: 202/522-3317

[1] The ―World Bank‖ refers to the International Bank for Reconstruction and Development (IBRD) and its affiliate, the International Development Association (IDA). Their procurement rules are identical.

References to IBRD ―loans‖ and IDA ―credits‖ are interchangeable.

How to Use These Forms

1. The evaluation forms and guide contained in this document provide step-by-step procedures for the evaluation of bids solicited through ICB. In all instances, the bidding and evaluation procedures described in the Instructions to Bidders (ITB) of the actual bidding document used should be followed.

2. ICB is conducted using the Standard Bidding Documents (SBDs)[1] issued by the Bank and required for use by Borrowers.[2] The following SBDs are currently available:

(a) Procurement of Goods (SBDG)
(b) Procurement of Works (referred to here as Larger Works) (SBDLW)
(c) Procurement of Works—Smaller Contracts (SBDSW)

Others are issued as Trial Editions or are yet in preparation. Bid evaluation procedures for the Trial Editions follow the procedures for the SBDG except for the SBD for Supply and Installation of Plant and Equipment, which is more similar to the SBDLW. The SBD for Commodities is based on modified ICB (see Section II.D of the *Guidelines*), in which bidding and evaluation procedures are based on one designated currency. The forms herein provided that deal with currency conversion may therefore be omitted.

3. Although each of the documents is different, their ITBs are very similar, particularly for the SBDG, SBDLW, and SBDSW, the most widely used documents. The following standard forms and guide are based on those ITBs, as well as on the Bid Data Sheets (BDSs), which follow the ITB and provide contract-specific information.

4. Readers should note that evaluation and the resulting report need not necessarily be lengthy. Procurement of off-the-shelf goods without domestic preference can usually be quickly and easily evaluated. In general, the complexity of evaluation lies with larger works and with the supply and installation of industrial plant and equipment. The forms should invariably accompany the evaluation report, but they may be adapted to suit specific requirements of the bidding documents. The report should include a number of attachments to explain details of bid evaluation or to show specific controversial wording or numbers in a bid. Cross-referencing should be used extensively, as well as references to pertinent clauses in the bidding documents.

5. Special mention should be made of contracts that group together (–package‖) smaller contracts (–lots‖—also called –slices‖ or –items‖), which may be awarded as a package to one bidder, or as sub-packages of one or more lots to several bidders. In such instances the bid evaluation is to be done separately, including any allowances for domestic preference, for

[1] See *Guidelines*, para. 2.12. When the relevant documents are not available, the use of other international documents may be acceptable to the Bank.

[2] –Borrower‖ refers here to the implementing agency, which may also be called the –Purchaser‖ or the –Employer.‖

each lot, subject to any cross-discounting (see Annex I, para. 7(b)). Only Tables 1, 2, and 3 will be common to all.

6. Borrowers should study these evaluation forms and guide during project preparation, in order to properly assess the managerial and administrative conditions needed for bid evaluation. Bank staff are available to explain the procedures, including any modifications necessary for evaluation using bidding documents other than those SBDs presently available. The Bank encourages the employment of experienced consultants to help in evaluations for complex contracts (see *Guidelines*, Appendix 1, para. 2(c)). Consultant fees can be paid from loan funds, if allowed for in the loan agreement.

3

Section I. Bid Evaluation Standard Forms

Bid Evaluation Report
and
Recommendation for Award of Contract

Name of Project: _____

IBRD Loan or IDA Credit No.: _____

Contract Name: _____

Identification Number: _____

Date of Submission: _____

Letter of Transmittal

If the contract is subject to prior review, the bid evaluation report should be attached with a Letter of Transmittal from the Borrower ministry, department, or agency responsible for communications with the Bank. The letter should highlight conclusions and offer any additional information that would help to expedite review by the Bank. In addition, any unresolved or potentially contentious issues should be highlighted. The letter should be sent to the Chief of the Sector Operations Division or the Country Operations Division responsible for the loan, unless another Bank official has been designated by the Bank for such correspondence.

Note: When subject to post review, the evaluation report and the signed contract should be submitted to the Bank before sending (or with) the pertinent Application for Withdrawal, Special Commitment, replenishment of the Special Account, or, in case of a Statement of Expenditures, retained for storage for eventual retrieval. (See *Guidelines*, Appendix 1, and the Loan Agreement.)

Table 1. Identification

1.1 Name of Borrower	
1.2 Loan/Credit number	
1.3 Date of effectiveness	
1.4 Closing date (a) original (b) revised	_____
1.5 Name of project	
1.6 Purchaser (or Employer) (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 _____ LIB _____ Other _____
1.11 Prior review required[2]	Yes _____ No _____
1.12 Domestic preference allowed	Yes _____ No _____
1.13 Fixed price contract	Yes _____ No _____
1.14 Cofinancing, if any: (a) agency name (b) percent financed by agency	_____

[1] Cite source and date if other than Staff Appraisal Report.
[2] If response is "no," items 2.2(b), 2.4(b), and 2.6(b) in Table 2 may be left blank, unless the Bank's prior review was specifically requested.

Table 2. Bidding Process

2.1 General Procurement Notice	
(a) first issue date	_____
(b) latest update	_____
2.2 Prequalification, if required	
(a) number of firms prequalified	_____
(b) date of Bank's no-objection	_____
2.3 Specific procurement notice	
(a) name of national newspaper	_____
(b) issue date	_____
(c) name of international publication	_____
(d) issue date	_____
(e) number of firms notified	_____
2.4 Standard Bidding Document	
(a) title, publication date	_____
(b) date of Bank's no-objection	_____
(c) date of issue to bidders	_____
2.5 Number of firms issued documents	_____
2.6 Amendments to documents, if any	
(a) list all issue dates	1._____ 2._____ 3. _____
(b) date(s) of Bank's no-objection	1._____ 2._____ 3. _____
2.7 Date of pre-bid conference, if any	
2.8 Date minutes of conference sent to bidders and Bank	_____

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, date sent to Bank	
3.4 Number of bids submitted	
3.5 Bid validity period (days or weeks)	
(a) originally specified	
(b) extensions, if any	_____
(c) date of Bank's no-objection, if required[1]	_____

Note: Contracts under two-stage bidding will require the information requested for each stage to be filled out. Refer to *Guidelines*, para. 2.6, and SBD for Supply and Installation of Plant and Equipment.

[1] Refer to Annex I, para. 3 herein.

Table 4. Bid Prices (as Read Out)

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

[1] For single currency option (see Annex I, 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. Refer also to Annex I, para. 2 herein.

Table 5. Preliminary Examination

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

Note: For explanations of headings, see Annex I, para. 5 herein. Additional columns may be needed, such as for responsiveness to technical conditions. See example in Annex IV.

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		Percent	Amount(s)	
(a)	*(b)*	*(c)*	*(d)*	*(e)*	*(f) = (c) + (d) - (e)*	*(g)*	*(h)*	*(i) = (f) – (h)*
etc.								

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* may be positive or negative.

[2] If the discount is offered as a percent, column *h* is normally the product of the amounts in columns *f* and *g*. Refer to para. 6(c). If the discount is provided as an amount, it is entered directly in column *h*. A price increase is a negative discount.

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.

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)*	Total Bid Price[2] *(f)*
etc.					

Note: This table is to be used for SBDG and Option B of 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)

Specify Evaluation Currency: _____

Bidder	Corrected/Discounted Bid Price (in specified currency)	Payment Composition[1]			Exchange Rate Used by Bidder[1]	Amounts in Currency of Payment	Exchange Rate for Evaluation[2]	Evaluation Currency	
		Currency of Payment	Percent of Total Bid	Amount in Evaluation Currency				Bid Prices	Total[3]
(a)	*(b)*	*(c)*	*(d)*	*(e) = (b) x (d)*	*(f)*	*(g) = (e) x (f)*	*(h)*	*(i) = (g) x (h)*	*(j)*
etc.									

Note: This table is used for SBDSW and Option A of SBDLW. Columns *a* and *b* are from Table 6, columns *a* and *i*.

[1] Columns *c*, *d*, and *f* are provided in the SBDLW Appendix to Bid and in the (Form of) Contractor's Bid in the SBDSW.

[2] Column *h* is from Table 7.

[3] Column *j* is the sum of bid prices in column *i* for each bidder.

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)*
etc.					

[1] Column *b* is from either Table 8, column *f* or Table 9, column *j*.

[2] Each insertion in columns *c*, *d*, or *e* should be footnoted and explained in adequate detail, accompanied by calculations. Refer to paras. 6(e), 6(f), and 6(g) respectively of Annex I

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)*
etc.								

[1] Column *b* refers to Groups A, B, or C, as indicated by bidder, subject to verification by Borrower.

[2] Column *c* is from Table 10, column *f*. If the lowest total price is from a Group A or Group B bidder, it is the lowest evaluated bidder, and the remainder of the table need not be filled out. Columns *d* through *h* need to be filled out only for Group C bids.

[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. Footnotes should be provided 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 percent of the CIF or CIP price. Refer to para. 7(a) of Annex I.

[5] Column *g* will be the smaller of 15 percent or the prevailing tariff in column *f*.

[6] Column *h* for Group A bidders is zero. Group B bids at this stage should no longer be compared. For Group C bidders, column *h* is the product of columns *e.g*.

Table 12. Domestic Preference for Works

Specify Evaluation Currency: _____

Bidder *(a)*	Domestic Preference Group[1] *(b)*	Total Price[2] *(c)*	Exclusions for Preference[3] *(d)*	Revised Total *(e) = (c) – (d)*	Preference[4] *(f)*	Total Comparison Price *(g) = (c) + (f)*
etc.						

[1] Column *b* refers to Group A (eligible domestic bidders) or Group B (others) as indicated by bidder, subject to verification by Borrower.

[2] Column *c* is from Table 10, column *f*. If the lowest priced bid is from a Group A bidder, it is the lowest evaluated bidder, and the remainder of the table need not be filled out.

[3] Column *d* is the sum of costs in columns *d* and *e* from Table 10. An attachment should be provided to explain the significant components of column *d*. Columns *d* and *e* may be left blank for Group A bidders.

[4] Column *f* for Group A bidders is zero. For Group B bidders, column *f* is 7.5 percent of column *e*.

Table 13. Proposed Contract Award

1.	Lowest evaluated responsive bidder (proposed for contract award). (a) name (b) address		
2.	If bid submitted by agent, list actual supplier. (a) name (b) address		
3.	If bid from joint venture, list all partners, nationalities, and estimated shares of contract.		
4.	Principle country(ies) of origin of goods/materials.		
5.	Estimated date (month, year) of contract signing.		
6.	Estimated delivery to project site/completion period.		
		Currency(ies)	Amount(s) or %
7.	Bid Price(s) (Read-out)[1]		
8.	Corrections for Errors[2]		
9.	Discounts[3]		
10.	Other Adjustments[4]		
11.	Proposed Award[5]		
12.	Disbursement Category[6]		

[1] From Table 6, columns *b* and *c*.

[2] From Table 6, column *d*.

[3] From Table 6, column *h*. Include any cross-discounts. See Annex I, para. 7(b).

[4] All adjustments should be explained in detail.

[5] Sum of the prices in Items 7–10. For single currency bids, express secondary currency amounts as percentages.

[6] From the Loan Agreement.

1. Identification, Bidding Process, and Bid Submission

Tables 1, 2, and 3 provide for the filing of basic information on the procurement process. This information is necessary to monitor compliance with the Loan Agreement, and particularly paras. 2.7 and 2.8 on advertising and notification of the *Guidelines*.

2. Bid Opening[1]

All bidders or their representatives are invited to attend the bid opening, where bids are read out and recorded, along with a list of attendees. The record is prepared for prompt transmittal to the Bank. Copies should be sent to all bidders. Bid opening procedures are described in the ITB. To assist in carrying out the opening and preparing of the record, a checklist is provided in Annex II. The checklist should preferably be filled out for each bid during the actual reading out at the meeting. The reading should be from the original version of each bid, and the actual amounts and other key details read out should be circled for later verification. If bids are expressed in a single currency, other currency needs expressed as a percentage should be recorded. It may also be desirable to read out exchange rates used by bidders (see para. 6(d)(ii) in this Annex).

Any envelopes containing substitutions, modifications, or withdrawals must be subject to the same level of scrutiny, including the reading out of critical details, such as price changes. Failure to read out such information and include it in the written record may result in denial of its inclusion in bid evaluation. If a bid has been withdrawn by cable, it should nonetheless be read out and should not be returned to the bidder until the authenticity of the withdrawal notice has been confirmed.

As stated in the ITBs, no bids should be rejected at the bid opening except those received after the deadline for receipt of bids. Such bids shall be returned unopened to the bidder. A summary of the read-out bid prices should be provided in Table 4.

3. Bid Validity

The duration of the validity of each bid should be the one specified in the ITB and should be confirmed in the signed (form of) bid. If exceptional circumstances occur in which award cannot be made within the validity period, extensions in writing should be requested of bidders, in accordance with the ITB (also *Guidelines*, para. 2.56). Extensions to the validity of bid security

[1] See *Guidelines*, para. 2.44. The record should be sent promptly to the Bank after bid opening and therefore does not usually accompany the bid evaluation report.

should also be requested of bidders, if necessary.[2] Note that for fixed price contracts subject to prior review, a no-objection by the Bank is necessary for extensions longer than sixty (60) days and for any subsequent extensions (*Guidelines*, Appendix 1, para. 2(d)).[3] Note any extensions in Table 3.

4. Principles of Evaluation

After the public opening of bids, information relating to the examination, clarification, and evaluation of bids shall not be disclosed to bidders or other persons not officially concerned with this process until the successful bidder is notified of the award of contract (*Guidelines*, para. 2.46). The Bank recommends appointment by the Borrower of an evaluation committee, consisting of a minimum of three qualified members who should work in a secure office where all bidding documents can be kept. There may be a considerable advantage if the same members participated in the preparation of the bidding documents.

On occasion, the Borrower may request clarifications of bidders concerning ambiguities or inconsistencies in the bid. As required in the ITBs, such requests shall be in writing, and no change in the price or scope of the originally offered goods, works, or services shall be sought or accepted, except for the correction of arithmetic error. The responses from bidders shall also be in writing. (Refer also to *Guidelines*, Appendix 4, para. 10.) No circumstances shall justify meetings or conversations between the Borrower (or its consultants) and bidders during the bid evaluation process.[4]

Bidders frequently attempt to contact the Borrower during bid evaluation, directly or indirectly, to query progress of evaluation, to offer unsolicited clarifications, or to provide criticisms of their competition. Receipt of such information should be acknowledged as to receipt only.[5] Borrowers must evaluate bids on the basis of the information provided in the respective bids. However, additional information provided may be useful in improving the accuracy, speed, or fairness of the evaluation. Nonetheless, no changes in the bid price or substance are allowed.

5. Preliminary Examination of

The evaluation process should begin immediately after bid opening. The purpose of preliminary examination is to identify

[2] Particular care must be taken in cases where the deadline for *submission* (or for opening) of bids can be extended, as the duration of bid security is frequently provided in terms of an expiration date. In contrast, bid validity is specified in terms of an interval after the deadline for receipt or the date of bid opening.

[3] Revised to eight (8) weeks, in the first (January 1996) reprint of the 1995 edition of *Guidelines*.

[4] See *Guidelines*, para. 2.6 for an explanation of two-stage bidding. If used, evaluation of the second-stage bidding follows the procedures in this *Evaluation Guide*.

[5] On occasion, bidders approach the Bank with information. Bank policy is to acknowledge the correspondence and pass it on to the Borrower for its consideration (*Guidelines*, Appendix 4, paras. 11–14).

Bids

and reject bids that are incomplete, invalid, or substantially nonresponsive to the bidding documents and therefore are not to be considered further. The following checks should be applied:

(a) Verification: Attention should be directed toward deficiencies that, if accepted, would provide unfair advantages to the bidder. Sound judgment must be used: for example, simple omissions or mistakes arguably occasioned by human error should not be grounds for rejection of the bid. Rarely is a bid perfect in all respects. However, the validity of the bid itself, for example, its signatures, must not be in question. If the bidder is a joint venture, the joint venture agreement must be submitted; if the bidder is an agent, an authorization from the supplier or manufacturer must be provided in addition to any documentation required of the supplier or manufacturer itself. All copies of the bid should be compared with the original and corrected accordingly, if necessary. Thereafter, the original should be kept in a safe location, and only copies should be used in evaluation.

(b) Eligibility: The bidder must be a national or a juridic entity from an eligible source country as defined in the Guidelines.6 All partners to a joint venture shall be from an eligible source country, and the joint venture shall be registered in an eligible source country. All goods and services shall originate from eligible source countries. In the case of plant and equipment, this eligibility test is applied only to the finished product offered in the bid and to its major and clearly identifiable components. If prequalification has taken place, only bids from prequalified bidders can be considered.[7] The bidder (including all members of a joint venture and subcontractors) may be disqualified if affiliated with a firm that has provided related consulting services on the project, or if the bidder is a publicly owned enterprise from the Borrower's country, lacking legal and financial autonomy. (See the ITB for details.)

(c) Bid Security: The bidding document may require submission of a bid security. If so, the bid security must conform to the requirements of the ITB, and it must accompany the bid. If the bid security is issued as a bank guarantee, it must be consistent with the wording of the bid.

[6] A list of eligible source countries and those subject to payment restrictions from the Bank loan are listed in Annex III.

[7] The juridic entities of the prequalified bidders may not be modified in the submission of bids.

security form provided in the bidding document. Submission of a copy of the security or submission of a counter guarantee naming the Borrower's bank instead of the Borrower is unacceptable. Furthermore, securities for an amount smaller or for a period shorter than the one specified in the ITB are not acceptable. The security for a bid submitted by a joint venture should be in the name of all of the partners of the joint venture.

(d) Completeness of Bid: Unless the bidding documents have specifically allowed partial bids—permitting bidders to quote for only select items or for only partial quantities of a particular item—bids not offering all of the required items should ordinarily be considered nonresponsive. However, under works contracts, missing prices for occasional work items are considered to be included in prices for closely related items elsewhere. If any erasures, interlineations, additions, or other changes have been made, they should be initialed by the bidder. They may be acceptable if they are corrective, editorial, or explanatory. If they are not, they should be treated as deviations and should be analyzed as per para. 5(e) below. Missing pages in the original copy of the bid may be cause for rejection of the bid, as may contradictions in model numbers or other designations of critical supply items.

(e) Substantial Responsiveness: Major deviations to the commercial requirements and technical specifications are a basis for the rejection of bids. As a general rule, major deviations are those that, if accepted, would not fulfill the purposes for which the bid is requested, or would prevent a fair comparison with bids that are properly compliant with the bidding documents. Examples of major deviations include:

(i) Stipulating price adjustment when fixed price bids were called for

(ii) Failing to respond to specifications by offering instead a different design or product that does not offer substantial equivalence in critical performance parameters or in other requirements

(iii) Phasing of contract start-up, delivery, installation, or

construction not conforming to required critical dates or progress markers

(iv) Subcontracting in a substantially different amount or manner than that permitted

(v) Refusing to bear important responsibilities and liabilities allocated in the bidding documents, such as performance guarantees and insurance coverage

(vi) Taking exception to critical provisions such as applicable law, taxes and duties, and dispute resolution procedures

(vii) Those deviations that are specified in the ITB as requiring rejection of the bid (such as, in the case of works, participating in the submission of another's bid other than as a subcontractor).

Bids that offer deviations may be considered substantially responsive—at least as to the issue of fairness—if the deviations can be assigned a monetary value that would be added as a penalty during the detailed evaluation process and if such deviations would be acceptable in the eventual contract.

The results of preliminary examination should be presented in Table 5. If the bid fails preliminary acceptance, the reasons must be clearly explained in footnotes or in an attachment, as necessary. An example is shown in Annex

IV. Borrowers may find it useful to include additional tables for itemization of responsiveness to a list of technical or commercial specifications. These should be attached to Table 5. Only those bids surviving preliminary examination need to be examined in this phase.

6. Detailed Examination of Bids

(a) Corrections for Errors: The methodology for correction of computational errors is described in the ITB. The read-out bid prices and their corrections should be noted in Table 6, column *d*. The corrections are considered binding on the

bidder. Unusual or large corrections that could affect the comparative ranking of bids should be explained in footnotes.

(b) Corrections for Provisional Sums: Bids may contain provisional sums set by the Borrower for contingencies or for nominated subcontractors, etc. As these sums are the same for all bids, they should be subtracted from the read- out prices in Table 6, column *e* to allow for a proper comparison of bids in subsequent steps. However, those provisional sums set aside for Daywork,[8] where priced competitively, should not be included in the deductions.

(c) Modifications and Discounts: In accordance with the ITB, bidders are allowed to submit, prior to bid opening, modifications to their original bid. The impact of modifications should be fully reflected in the examination and evaluation of the bids. These modifications may include either increases or discounts to the bid amounts that reflect last-minute business decisions. Accordingly, the original bid prices should be modified at this point in the evaluation. Discounts offered in accordance with the ITB that are conditional on the simultaneous award of other contracts or lots of the contract package (cross-discounts) shall not be incorporated until the completion of all other evaluation steps. The effect of unconditional discounts (or alternatively, increases) should be shown as in Table 6 (columns *g* and *h*). Any discount expressed in percent must be applied to the appropriate base specified in the bid (i.e., check to see if it applies to any provisional sums).

(d) Evaluation Currency: The remaining bids as corrected for computational errors and as adjusted for discounts should be converted to a common evaluation currency, as described in the ITB. The exchange rates to be used in the calculations are to be listed in Table 7. If multiple exchange rates exist for a particular currency (for commercial, government transactions, etc.), indicate which applies, with reasons for the choice. Where exchange rates for a particular currency are not available from the specified authority or publication, identify the secondary source, as well as any necessary conversion calculations.

There are two different currency options for bidding/payment, each requiring a different conversion

[8] Refers to unforeseen work. For details, see SBDLW, Section B, or SBDSW, Section 7.

methodology:

(i) The SBDG and Option B of SBDLW use the multiple currency option, in which the bid price is expressed in a number of currencies. For this procurement, use Table 8.

(ii) The SBDSW and Option A of SBDLW use the single currency option, in which the bid price is expressed entirely in a specific currency, usually in the Borrower's currency, with other foreign currency requirements stated as percentages of the bid price, together with the exchange rates used by the bidder to determine the percentages. For SBDLW single currency bids, sections of the Works may require payment in different currencies and proportions. In such instances, the impact of any corrections found will require a lengthier analysis for each bid, based on the submitted Appendix to Bid. Table 9 is to be used for these calculations.

(e) Additions: Omissions to the bid should be compensated for by adding the estimated costs for remedying the deficiency. Where items missing in some bids are present in others, an average of quoted prices could be used to compare competitors' bids. Alternatively, external sources, such as published price lists, freight tariff schedules, etc., may be appropriate. The cost determined should be expressed in the evaluation currency and shown in Table 10, column *c*.

(f) Adjustments: The ITB specifies which, if any, performance or service factors will be taken into account in the bid evaluation (see, for example, para. 26 of SBDG). The methodology used in evaluation of these factors should be precisely described in the bid evaluation report and should be fully consistent with the ITB provisions. Bonuses or additional credits that reduce the evaluated bid price will not be given in the bid evaluation for features that exceed the requirements stated in the bidding documents, unless specifically provided for in the ITB.[9] The value of adjustments will be expressed in terms of cost, for all works and most goods contracts, and should be shown in Table 10,

[9] Similarly, a bid offering a choice of different product models is evaluated on the basis of the lowest price offered by the bidder from among the models meeting the requirements of the bidding document.

column *d* and expressed in the evaluation currency.[10]

(g) Priced Deviations: As discussed under para. 5(e), bids with minor deviations may be considered substantially responsive if their further consideration assigns a monetary cost or penalty to the bid for the purpose of bid comparison:

- Requests for deviations that are expressed by the bidder in vague terms, such as ―we would like an increase in the amount of mobilization advance‖ or
  ―we wish to discuss changes in the completion schedule‖ should ordinarily be ignored in bid evaluation. However, a categorical statement by the bidders taking exception to a requirement in the bidding documents should be treated as a deviation.
- If a bid requires a faster payment stream than specified in the bidding documents, the penalty is based on the prospective benefit to the bidder. This situation assumes use of a discounted cash flow using the prevailing commercial interest rates for the currencies of the bid, unless the ITB foresees the eventuality and specifies a rate.
- If a bid provides for a delivery or completion that is beyond the date specified in the bidding documents but that is nonetheless technically acceptable to the Borrower, the time advantage given should be assessed a penalty specified in the ITB or, if one is not provided, based on the rate of liquidated damages specified in the bidding documents.

The deviations should be priced in the evaluation currency in Table 10, column *e*.

7. Determination of Award

In the comparison of bids for works and for most goods, the corrected and discounted bid prices, together with adjustments for omissions, deviations, and specified evaluation factors, have been noted in Table 10. The bidder with the lowest total is the lowest evaluated cost bidder at this stage, subject to:

- Application of domestic preference, if any is allowed;

[10] The Bank on occasion may allow the use of the Merit Point System for the purchase of goods. If so, the adjustments will be expressed in points. Refer to ITB (para. 26.5) of the SBDG and to the Bank directly for details on bid evaluation using the point system.

- Application of any discounts, contingent on the simultaneous award of multiple contracts or lots; and
- Post qualification evaluation, or, if prequalification has occurred, confirmation of prequalification information.

(a) Domestic Preference: If domestic preference is allowed in bid evaluation, the ITB will so state and provide detailed procedures to be used in determining the eligibility for preference and the amounts.

(i) With respect to goods contracts, verification of the prevailing import duties and the related import taxes to a nonexempt importer must be made. If these duties and taxes are less than 15 percent of the CIF or CIP price,[11] they are to be used as to the amount of preference. Also, the eligibility of goods for domestic preference must be examined according to the criteria described in the ITB.[12]

The calculations for determining the lowest evaluated bidder are based on a two-step process. In the second step, if needed, the domestic preference is *added* (like a tariff) to the CIF or CIP bid prices of the goods offered from abroad.[13] Care should be taken to separate these prices from the overall bid prices, which may include the costs of internal transportation and related freight insurance, installation, training, and other costs incurred within the Borrower's country. Such costs are not to be adjusted for the preference. The CIF or CIP bid prices used will reflect corrections for errors and discounts and will be adjusted for omissions pertaining to the CIF or CIP prices (such as insufficient spare parts). They will *not* reflect adjustments for deviations or specified evaluation factors. The preference tariff calculated will then be added to the corrected, discounted, and adjusted total prices tabulated in Table 11.

[11] CIF is cost, insurance and freight for maritime transportation. CIP is cost, carriage and insurance in the case of multimodular transportation. For further definitions, refer to *INCOTERMS 1990*, International Chamber of Commerce, 38 Cours Albert 1er, 75008 Paris, France.[12] In the case of single responsibility supply and installation of plant and equipment, the domestic preference applies to individual components of the bid. Procedures in such cases are described in the *Guidelines*, Appendix 2, para. 6, and if applicable to the procurement under review, would be embodied in the ITB.

[13] This occurs if the apparent low bidder from the first step is importing the goods.

All calculations involved in assessing domestic preference should be clearly shown in Table 11, together with accompanying explanations as necessary. The lowest evaluated bidder would be the bidder with the lowest price total in column *i*, unless note 2 of Table 11 applies.

(ii) Any domestic preference eligibility allowed under works contracts is dependent on ownership criteria and on the share of work to be undertaken. The domestic preference is provided by adding 7.5 percent to the corrected and discounted bid prices of bidders not eligible for domestic preference. The ITB excludes domestic preference application to any provisional sums, as well as to adjustments or priced deviations. The lowest evaluated bidder is the bidder with the lowest total in column *g* of Table 12.

(b) Cross-Discounts: These are conditional discounts offered in the event that more than one contract or lot will be awarded to the same bidder. Bid evaluation in such cases can be quite complicated, particularly for goods contracts where domestic preference may apply. The sizes of cross-discounts offered by each bidder may vary with the potential number of contracts awarded. The ITB may also limit the number or total value of awards to a bidder on the basis of its financial and technical capacity.[14] Thus, a bidder offering the lowest evaluated bid on a particular contract may be denied award because of such a restriction. The Borrower shall select the optimum combination of awards on the basis of least overall cost of the total contract package, consistent with the qualification criteria. (Refer to *Guidelines*, para. 2.4.) Presentations of the calculations should be made on an attachment to the report, which should include the bid evaluation(s) for the other contracts, if they have been evaluated separately.

(c) Qualification: If prequalification was conducted, the bidder whose bid is the lowest evaluated should receive the award, unless the bidder's qualifications have since materially deteriorated or the bidder has since received additional work that overstresses its capacity. The Borrower should satisfy itself fully on both accounts.

Where prequalification has not occurred, the prospective

[14] This restriction may originate with prequalification.

awardee should be subjected to post qualification, the procedures for which are described in the ITB.[15]
If the lowest evaluated bidder fails post qualification, its bid should be rejected, and the next ranked bidder should then be subject to post qualification examination. If successful, this bidder should receive the award. If not, the process continues. (Refer to *Guidelines*, para. 2.57.)
The rejection of a bid for reasons of qualification requires substantial justification, which should be clearly documented in attachments to the report. A history of poor performance may be considered a substantial justification.

(d) Alternative Bids: The ITB may request or allow the Borrower to accept alternative bids under the stipulation that only the alternative submitted by the lowest evaluated bidder and conforming to the bidding documents will be considered.
   (i) For works, the ITBs may allow alternative technical solutions and/or alternative times for completion.
   (ii) For goods, the ITB may allow for submission of an alternative payment schedule. The same ITB (paras. 11.2(b)(ii) or (iii)) may also require bidders to submit, in addition to any CIF or CIP bids, similar bids less transport or insurance, such as FCA or CFR.[16] The Borrower, if it is willing to accept the alternative bid offered by the lowest evaluated bidder, should provide justification for doing so.[17]

Calculations for the evaluation of alternatives should be provided in an attachment to the report.

(e) Proposed Award: The amount of the proposed award shall be the bid price as submitted by the winning bidder and adjusted as described in the ITB for corrections, any discounts (including cross-discounts), and acceptance by the Borrower of alternative offers from the lowest evaluated bidder. Adjustments to the final price and scope of the

[15] The Annex in the Bank's Standard Prequalification Document is useful for post qualification evaluations.

[16] *INCOTERMS 1990*.

[17] If the contract is signed without insurance coverage, the Borrower must provide the Bank with evidence of alternative insurance payable in a freely usable currency to replace or repair such goods (*Guidelines*, para. 2.27, and General Conditions of the Loan or Credit Agreement).

Contract to correct for acceptable omissions and quantity variations in the bid may be negotiated with the lowest evaluated bidder.[18] Prior concurrence of the Bank with the proposed award is required before such negotiations may be entered into (*Guidelines*, para. 2.62). Table 13 should be filled out to establish the actual amount of the contract award. If (a) none of the bids are found to be responsive, (b) bids are unreasonably high in price compared with earlier estimates, or (c) none of the bidders are qualified, the Borrower may consider rejection of all bids (prior Bank concurrence is required) (*Guidelines*, paras. 2.59–2.62).

(f) Report Submission

(i) *Prior Review*: In accordance with the loan agreement, the Borrower must submit the completed bid evaluation report containing the required summary to the Bank as soon as possible after bid opening, preferably no later than three (3) weeks prior to the expiration of the bid validity period. The report should include the appropriate items listed in Annex V.

Borrowers are encouraged to request assistance as needed from the Bank in explaining the evaluation procedures. However, the Bank will not participate in the evaluation itself.

(ii) *Post Review*: For contracts not subject to prior review, the Borrower may award the contract upon completion of bid evaluation (*Guidelines*, Appendix 1, para. 4). As stated therein, subsequent submission of the bid evaluation report to the Bank is required prior to delivery of a withdrawal application, or if a Special Account is used, prior to its first replenishment application. These provisions do not apply if Statements of Expenditures are used, whereby the evaluation and other documents are kept by the Borrower, subject to future review by the Bank.

(g) Review by the Bank: Upon receipt by the Bank, all contracts subject to prior review will be reviewed. Borrowers may be requested to provide additional

[18] Note that SBDG—ITB para. 31 allows the Purchaser (Borrower) the right to unilaterally vary quantities within set limits at the time of award.

information and justification for the recommendations. The Bank will not contact bidders. However, it may request the Borrower to do so for necessary clarifications. When the Bank is satisfied with the evaluation of bids and recommendations of award, a ―no-objection‖ written communication will be issued by the Bank official designated for such correspondence.

For contracts subject to post review, any doubts about the justification for award should be raised with the Bank prior to award signing. Borrowers should ensure that all correspondence received from bidders concerning evaluation has been taken into account. The Bank does not finance contracts that have not been procured in accordance with the loan agreement.[19]

(h) Award of Contract: Bid securities of unsuccessful bidders should be returned promptly after award has been made. However, if contract effectiveness is contingent on the receipt of a performance security or other condition, the Borrower may consider seeking an appropriate extension of time for the bid validity and the accompanying bid security of the next two lowest bidders.

As mentioned in the Preface, upon confirmation by the Borrower that the award has been made, the Bank is authorized to publish a description of the contract, the name and nationality of the contract awardee, and the contract price. Any further information on the bids or on their evaluation, including the bid evaluation report, is held in confidence by the Bank. Unsuccessful bidders are allowed under the *Guidelines* (Appendix 4, para. 15) to seek a debriefing with the Borrower, and, additionally, with the Bank. In anticipation of this and/or any post reviews by the Bank, the Borrower should ensure that bidding documents and evaluations are securely stored.

[19] If funds from the loan have already been disbursed, the Bank may seek reimbursement. Refer to *Guidelines* para. 1.13 and Appendix 4, para. 3.

Annex II. Bid Opening Checklist

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

Contract Reference: _____

Bid Opening Date:_____ Time: _____

Name of Bidder: _____

(a) Is outer envelope of bid sealed?

(b) Is bid form completed and signed?

(c) Expiration date of bid:

(d) Is documentary authority for signing enclosed?

(e) Amount of bid security (if required): _____(state currency)

(f) Describe any ―Substitution,‖ ―Withdrawal,‖ or ―Modification‖ submitted

(g) Describe any alternative bid made:

(h) Describe any discounts or modifications offered:

(i) Additional comments:[1]

(j) Name of bidder or representative present:

(k) Total bid price:_____(list currencies and amounts or percentages)[2]

(l)

Signature of responsible official:_____ Date: _____

[1] Read out and record model numbers of equipment.

[2] If bid is for a package of contracts, the price for each lot or item should be read out.

Annex III. Eligibility for the Provision of Goods, Works, and Services in Bank-Financed Procurement

As of January 1998

For the information of borrowers and bidders, and with reference to paragraph 1.6, footnote 9, of the *Guidelines: Procurement under IBRD Loans and IDA Credits*, dated January 1995,

revised January and August 1996, and September 1997, set forth below is a list of countries from which bidders, goods, and services are not eligible to participate in procurement financed by the bank or IDA.[1]

- Andorra
- Cuba
- Democratic People's Republic of Korea (North Korea)
- Liechtenstein
- Monaco
- Nauru
- San Marino
- Tuvalu

In addition, bidders, goods, and services from other countries or territories may be declared ineligible by a provision in bidding documents if the borrower's country has excluded them by a law, official regulation, or act of compliance meeting the requirements of paragraph 1.8(a) of the *Guidelines: Procurement under IBRD Loans and IDA Credits*.

The Loan Agreement also prohibits a withdrawal from the Loan for the purpose of any payment to persons or entities, or for any import of goods, if such payment or import, to the knowledge of the Bank, is prohibited by a decision of the United Nations Security Council taken under Chapter VII of the Charter of the United Nations. At the present time, this prohibition applies to:

- Iraq
- Libya

[1] Any questions regarding this list should be addressed to the Senior Manager, Procurement Policy and Services Group, Operational Core Services Networ

Preliminary Examination

Bidder	Verification	Eligibility	Bid Security	Completeness of Bid	Substantial Responsiveness	Acceptance for Detailed Examination
Bidder A	Yes	Yes[1]	Yes	Yes	Yes	Yes
Bidder B	No[2]	Yes	Yes	Yes	Yes[3]	No
Bidder C	Yes[4]	Yes	Yes	Yes	Yes	Yes
Bidder D	Yes	Yes	No[5]	No[6]	Yes	No
Bidder E	Yes	No[7]	No[8]	Yes	Yes	No
Bidder F	Yes	Yes	Yes	Yes	Yes	Yes
Bidder G	Yes	Yes	Yes	Yes	Yes	Yes
Bidder H	Yes	Yes	Yes	Yes	Yes[9]	Yes

[1] Bidder is partly owned (25 percent) by government (of Borrower). It operates under commercial law and is financially and managerially independent of government.
[2] Joint venture agreement missing.
[3] Requires 25 percent mobilization advance; bid document states maximum of 15 percent. Deviation is minor and can be quantified.
[4] Bidder prequalified as local agent; bid is joint obligation with parent company. Bid deemed acceptable because increase in financial backing results.
[5] Bid security not in freely convertible currency.
[6] Does not include cost for required disposal of hazardous wastes found at the site.
[7] Source of plant from non-eligible country.
[8] Required validity period of security not met (8 weeks instead of 12 weeks).
[9] Contains several initialed changes substituting ISO standards in the specifications with DIN standards. This is acceptable to the Engineer-in-Charg

Annex V. Bid Evaluation Summary Checklist

1. Attach bid opening record, if not previously submitted (refer to footnote 1, Annex I).
2. Explain any inconsistencies between prices and modifications to prices read out at bid opening (and written into the record) and presented in Table 4.
3. Provide details on eliminating any bids during preliminary examination (Table 5). Copy select pages from bids, as desirable, to show examples of objectionable features.
4. If provisional sums in Table 6 vary among bidders, explain. Explain any substantial corrections for computational errors that may affect the ranking of bidders.
5. Provide a copy of the rates requested for Table 7 and used in Tables 8 or 9.
6. The additions, adjustments, and priced deviations in Table 10 require detailed explanations where they may affect the ranking of bidders.
7. Eligibility for domestic preference as indicated in Tables 11 or 12 must be verified if the ranking of bids is affected. Provide details in an attachment. Exclusions to the calculations for preference should be explained if similarly significant.
8. Explain any cross-discount (para. 7(b)) not read out and recorded at bid opening. In addition, attach copies of any evaluation reports for the other related contracts awarded to the same bidder.
9. Provide detailed reasons for refusing to award a contract to a party other than the lowest evaluated bidder (para. 7(c)).
10. If an alternative bid is accepted, provide a detailed explanation of the reasons for its acceptance, addressing issues of timeliness, performance, and cost implications (para. 7(d)).
11. An attachment to Table 13 should explain adjustments to the price provided on line
12. Explain any changes to scope of bid and contract conditions.
13. Provide evidence of alternative insurance (see footnote 17, Annex I).
14. Attach copies of any correspondence from bidders that raise objections to the bidding and evaluation process, together with detailed responses.
15. Attach copies of any letters to bidders requesting clarifications. Provide copies of responses.
16. Submit bid evaluation with separate evaluation report from consultant, if one was commissioned.
17. Ensure that the bid evaluation report is double-checked, paginated, and complete, and includes a Letter of Transmittal. The Bank will only review reports that are sent to it by the proper authorities.
18. Send by courier or by other swift means.

Frequently Asked Questions

Is it essential that the Tender in Newspaper and on Web site should be displayed on the same date?

Not necessarily but it's an efficient way to published & upload the Tender. Under sub section [3] of Rule 14 of PPRA Rules 2014 response time shall be calculated from the publication of advertisement in a newspaper or on the website, whichever is later.

When Tender uploading fee must be deposited in the bank?

Tender uploading fee must be deposited in the bank before uploading the tender on the website.

What is difference among Gallop Tender Notice, Short Tender Notice & Tender Notice?

There is no provision of Gallop Tender Notice and Short Tender Notice in PPRA Rules 2014.

What does Bid means?

Bid means a Tender, an offer, in response to an invitation, by a person, consultant, firm, company or an organization expressing his or its willingness to undertake a specified task at prices.

What is the minimum response time for procurement advertisements?

In terms of Rule 14 of the Punjab Procurement Rules 2014 the minimum response time shall not be less than fifteen (15) days for national competitive bidding and thirty (30) days for international competitive bedding. The Procuring Agencies can increase the response time depending upon nature of procurement.

How can procuring agency calculate response time?

The response time shall be calculated from the date of first publication of the advertisement in newspaper or posting on the PPRA's website. In case if the advertisement is mandatory to advertise in both print and PPRA website in terms of Rule 12 of Punjab Procurement Rules, 2014 the response time shall be calculated from the day of last publication either in newspaper or PPRA website.

When the Bid must be opened?

The date of opening of bids and the last date for the submission of bids shall be the same. Bids shall be opened in the presence of bidders or their representatives at the time specified in the bidding documents. The bids shall be opened atleast thirty minutes after the deadline for submission of bids.

Can procuring agency fix amount for bid security?

In terms of Rule 27 of the Punjab Procurement Rules 2014 the procuring agency may require the bidders to furnish a bid security not exceeding five percent of the bid price. The procuring agencies cannot fix the amount on account of bid security.

Can procuring agency reject bids without assigning any reason?

In terms of Rule 35(1) of the Punjab Procurement Rules 2014 the procuring agency may reject all bids or proposals at any time prior to the acceptance of a bid or proposal. The procuring agency shall immediately give notice of rejection of bid(s) to all bidders. On request by the bidders, the Procuring Agency shall intimate the reasons of rejection of bids but will incur no liability on this account nor is required to justify the rejection of bids.

What course of action will be adopted by the procuring agency when all the bids prices substantially exceed the cost estimated/market value?

The procuring agency is allowed to cancel all the bids prior to acceptance as provided under Rule-35 of the Punjab Procurement Rules, 2014 and invoke Rule 36 of the said Rules for re-bidding.

Whether the procuring agency can enter into negotiations with the bidders for the reduction in the prices or to call for new bids?

Negotiations with the bidder having submitted the lowest evaluated bid or with any other bidder are not allowed as provided under Rule 40 of Punjab Procurement Rules, 2014.

Is negotiation if allowed to be made with all the bidders or only with the lowest evaluated bidders?

Negotiations are not allowed as provided under Rule 57 of Punjab Procurement Rules, 2014.

How to Upload Tender Documents at PPRA's Web site?

By Online:
User ID and Password provided on request for online tender submission by the department itself.
By Post:
Soft copies of Tender documents alongwith deposit slip can be sent by Post/Courier to PPRA, if a procuring agency does not have a User ID and Password.

It is not clear whether all annual requirements if known would have to be advertised in advance on PPRA's website or just the main items?

Indicative requirements of annual procurement should be advertised under Rule 8, at macro level, on PPRA's website as well as on the website of the organization concerned for advance information of prospective bidders. Detailed advertisement for processing the procurements should subsequently be made, as required from time to time, in accordance with Rule 12.

If a tender for procurement of goods over one hundred thousand rupees and up to the limit of two million rupees is launched on Authority's website, would there be any compulsion on the procuring agency to advertise it in the print media also?

It is not mandatory to put the advertisement on print media.

If only one tender/bid is received in response to a tender notice advertised in both or one of the media (Authority's website/ print media), should the single tender be accepted or the tender is re-advertised?

Punjab Procurement Rules, 2014 don't put any limit on number of tenders/ bids received in response to tender notices provided that the procurement opportunity has been advertised in the prescribed manner. The single bid may be considered if it meets the evaluation criteria expressed in tender notice and is not in conflict with any other rules, regulations or policy of the Punjab Government. However the procuring agency should make a decision with due diligence and in the light of Rule 4 "Principles of Procurement".

How to compare the only one bid received by a procuring agency?

Whenever a procuring agency is confronted with such a situation whereby the rate quoted by the single bidder cannot be compared so as to declare it as the lowest rate or otherwise it may make a prudent decision. While making a decision, the following factors may be kept in view:

- The comparison of price of the goods, works or services if procured during the current financial year.
- Market price of the goods works and services to be procured.
- In case abnormal Increase in prices is observed, the procuring agency may like to re-advertise the procurement opportunity, if time permits.

If no tender/ bid is received against a requirement, what method of procurement is recommended to be adopted (Re-advertisement or Direct Contracting)?

Re-advertisement would be a preferred option. Direct contracting could also be used provided it meets the prescribed condition for direct contracting.

Under the Rule if preference was allowed to a domestic or national supplier/contractor, magnitude of price preference to be accorded should be mentioned. However, a clarification whether the magnitude of price preference should be in figure or the percentage needs to be obtained?

Preference to domestic or national suppliers or contractors should be in accordance with policies of the Punjab Government.

It has been observed that financial limits for procurement under sub rules (a) & (b) are not sufficient. Do these limits need to be reviewed?

The sub rule (a) of Rule 59 includes provision which reads as "Provided further that procuring agencies convinced of the inadequacy of the financial limit prescribed for petty purchases in undertaking their respective operations may approach the Punjab Government for enhancement of the same with full and proper justifications". Likewise sub rule (b) of Rule 42 includes provision which reads as "Provided that procuring agencies convinced of the inadequacy of the financial limit prescribed for request for quotations in undertaking

their respective operations may approach the Punjab Government for enhancement of the same with full and proper justifications." Accordingly the procuring agencies may send a proposal for consideration of PPRA Board.

Under sub rule c(iv) a procuring agency may engage in direct contracting for repeat orders not exceeding fifteen percent of original procurement. It is not clear how this rule could be applied in case of procurement of spare parts/equipment.

Procurement of spare parts has been dealt with separately under Rule 59(c)(i) which reads as "A" procuring agency shall only engage in direct contracting if he following conditions exist, namely:-
The procurement concerns the acquisition of spare parts or supplementary service from original manufacturer or supplier:
Provided that the same are not available from alternative sources;
In case of procurement of spare parts/equipment through open competitive bidding when spare parts of required specifications are available from multiple sources, repeat orders not exceeding fifteen percent of the original procurement of the spare parts/equipment may be placed under rule 59(c)(iv).

What is mis-procurement?

Any violation of PPRA Rule 2014 shall amount to mis-procurement.

In case different bidders quote prices partly, how such bids can be evaluated?

A procuring agency shall announce in an appropriate manner all proposed procurements for each financial year and shall proceed accordingly without any splitting or regrouping of the procurements so planned.

Due to immediate need of security of data involved, can a procuring agency adopt the method of direct contracting on Pro-tem basis with an exclusive experienced firm?

Under Rule 59(ii) of PPRA Rules 2014, A procuring agency may engage in direct contracting with a single firm/ manufacturer or supplier, but coupled with extreme security reasons.

Can a procuring agency award a contract to the firm item wise lowest bidder? In case of goods procurement?

A procuring agency after formulation / categorization of different goods into different packages may award contract to the lowest bidder for a package without splitting under Rule 09 of PPRA Rules 2014.

If a bidder has not submitted the required document with the technical bid as per evaluation criteria, and later submitted after closing time, can it be considered as a responsive bidder?

The bidder in terms of Rule 12 (1) of PPRA Rules 2014 required to provide all requisite document along with bid before the closing time. He cannot be allowed to submit any missing document to become confirmer to the laid down criteria and shall be disqualified for equity aids the vigilant. The procuring agency shall not open the financial bid to non-responsive bidder.

How can a procuring agency determine the price of the bidding documents?

A procuring agency in term of Rule 25(7) of PPRA Rules, 2014 can charge the fee in view of the cost of printing and provision of documents. Any irrational / excessive price fixing since can curtail competition, therefore must be avoided.

If a procuring agency intends to enhance the version of any software, can it be allowed for direct contracting?

The software purchased from the original manufacturer can be enhanced from the same source in terms of Rule 59(c) of PPRA Rules, 2014, to avoid compatibility issues and operational problems.

If a procurement include both sea & air freight cost changes, then what will be the preferred mode of selecting successful bidder?

A procuring agency should prudently determine the delivery time keeping in view its requirement as both Sea & Air transportation involve huge cost difference. The procuring agency should calculate the difference in transportation cost w.r.t. require delivery time and select the one, which ensures economy and efficiency in the procurement.

Can a new contract for similar procurement be made with the successful bidder of the procurement conducted during last / previous year, for this financial year?

In terms of Rule 8 of PPRA Rules, 2014 procuring agency should make its procurement in accordance with the procurement plan. The procurement conducted last year was on the basis of requirement of that particular year. Hence for abundant caution and financial prudence demands that procurement in the current financial year should be made afresh as the cost determining factors (quantity time, rate of exchange, inflation etc.) various from procurement to procurement.

Can a procuring agency adopt partial bidding process used by some other procuring agency for the same nature of procurement?

PPRA Rules do not obstruct any process conducted by any procuring agency for similar procurement. But for abundant caution procuring agency can in addition to already prequalified bidders invite EOI from other bidders, and if no response comes back then it can take already prequalified bidder on board.

If a bidder has submitted the photocopy of bidding documents though he purchases the original documents, can he be disqualified from participating in procurement process?

The bid presented on photocopy of bidding documents with original receipt and signature is a valid document authorizing the bidder to participate in competition. He cannot be disqualified on the aforementioned grounds.

Project Management Unit (PMU)
REVAMPING OF DHQ /THQ HOSPITALS IN PUNJAB

B I D D I N G D O C U M E N T

Primary & Secondary Healthcare Department

GOVERNMENT OF THE PUNJAB

September 2020

Invitation for Bids

Dated: 4th Sept, 2020

1. The Project Management Unit (PMU) has received budget from Government of Punjab towards the cost of Revamping of DHQ /THQ Hospitals in Punjab. It is intended that part of the proceeds of this budget will be applied to eligible payments under the contract for supply of following items:

Package -1	Item	Qty	Bid Security

2. The PMU now invites sealed bids from eligible bidders, Manufacturers, authorized Sales & Service Dealers for the supply of above mentioned items.

3. Bidding shall be conducted through Open Competitive Bidding (Single Stage-Two Envelope) procedures specified in the Punjab Procurement Rules PPRA 2014 (amended Jan 2016), and is open to all eligible bidders as defined in the bidding document

4. Interested eligible bidders may obtain bidding documents and further information from the **Office** of **Procurement Specialist,** Project Management Unit, Revamping of DHQ /THQ Hospitals, 31/E1, Shahra-e-Imam Hussain, Gulberg III, Lahore or download from website: www.pshealth.punjab.gov.pk

5. The provisions in the Instructions to Bidders and in the General Conditions of Contract are the provisions of the Bidding Documents.

6. Sealed Bids must be delivered to the above office **on or before 11:00 a.m. on 22th September, 2020** and must be accompanied by a **Bid Security as mentioned above** in the form of CDR, Pay Order, Demand Draft, or Banker's Cheque from a Scheduled Bank of Pakistan.

7. **Bids will be opened in the presence of bidders' representatives who choose to attend at 11:30 a.m.** in the Office of **Procurement Specialist,** Project Management Unit, 31/E1, Shahra-e-Imam Hussain, Gulberg III, Lahore **on the same date.**

8. The bidders are requested to give their best and final prices as no negotiations are expected.

9. Taxes will be deducted as per applicable government rules. NTN and Sales Tax registration certificate must be provided.

10. For obtaining any further information or clarifications, please contact the person named below:

Procurement Specialist
Project Management Unit (PMU)
Revamping of DHQ /THQ Hospitals in Punjab
Primary & Secondary Health Department
Government of the Punjab
31-E/1, Shahra-e-Imam Hussain, Gulberg-III, Lahore
Tel: 042-99231202
Website: www.pshealth.punjab.gov.pk
E-mail: procurement.pmu.psh@gmail.com

Table of Contents

Part-I

Section I. Instructions to Bidders

A. Introduction

1. Source of Funds	1.1 The Procuring Agency named in the Bid Data Sheet has received budget from the Government of Punjab. The Procuring Agency intends to apply a portion of the proceeds of this budget to eligible payments under the contract for which this Invitation for Bids is issued
2. Eligible Bidders	2.1 This Invitation for Bids is open to all suppliers, except as provided hereinafter. 2.2 Bidders should not be associated, or have been associated in the past, directly or indirectly, with a firm or any of its affiliates which have been engaged by the Procuring Agency to provide consulting services for the preparation of the design, specifications, and other documents to be used for the procurement of the goods to be purchased under this Invitation for Bids. 2.3 Government-owned enterprises may participate only if they are legally and financially autonomous, if they operate under commercial law, and if they are not a dependent agency of the Government. 2.4 Bidders shall not be under a declaration of blacklisting by any Government department or Punjab Procurement Regulatory Authority (PPRA).
3. Eligible Goods and Services	3.1 All goods and related services to be supplied under the contract shall have their origin in eligible source countries, defined in the *Bid Data Sheet (BDS)*, and all expenditures made under the contract will be limited to such goods and services. 3.2 For purposes of this clause, "origin" means the place where the goods are mined, grown, or produced, or the place from which the related services are supplied. Goods are produced when, through manufacturing, processing, or substantial and major assembly of components, a commercially-recognized product results that is substantially different in basic characteristics or in purpose or utility from its components. 3.3 The origin of goods and services is distinct from the nationality of the Bidder.
4. Cost of Bidding	4.1 The Bidder shall bear all costs associated with the preparation and submission of its bid, and the Procuring Agency named in the Bid Data Sheet, hereinafter referred to as "the Purchaser," will in no case be responsible or liable for those costs, regardless of the conduct or outcome of the bidding process.

B. The Bidding Documents

5. Content of Bidding Documents	5.1 The goods required, bidding procedures, and contract terms are prescribed in the bidding documents. In addition to the Invitation for Bids, the bidding documents include: (a) Instructions to Bidders (ITB) (b) Bid Data Sheet (c) Schedule of Requirements

	(d) Technical Specifications (e) Bid Submission Form (f) Manufacturer's Authorization Form (g) Price Schedules (h) Contract Form (i) Performance Security Form (j) General Conditions of Contract (GCC) (k) Special Conditions of Contract (SCC) 5.2 The Bidder is expected to examine all instructions, forms, terms, and specifications in the bidding documents. Failure to furnish all information required by the bidding documents or to submit a bid not substantially responsive to the bidding documents in every respect will be at the Bidder's risk and may result in the rejection of its bid.
6. Clarification of Bidding Documents	6.1 A prospective Bidder requiring any clarification of the bidding documents may notify the Purchaser in writing or by email at the Purchaser's address indicated in ITB Clause 19.1. The Purchaser will respond in writing to any request for clarification of the bidding documents which it receives no later than three (3) days prior to the deadline for the submission of bids prescribed in the Bid Data Sheet. Written copies of the Purchaser's response (including an explanation of the query but without identifying the source of inquiry) will be sent to all prospective bidders that have received the bidding documents
7. Amendment of Bidding Documents	7.1 At any time prior to the deadline for submission of bids, the Purchaser, for any reason, whether at its own initiative or in response to a clarification requested by a prospective Bidder, may modify the bidding documents by amendment. 7.2 All prospective bidders that have received the bidding documents will be notified of the amendment in writing or by email, and will be bidding on them. 7.3 In order to allow prospective bidders reasonable time in which to take the amendment into account in preparing their bids, the Purchaser, at its discretion, may extend the deadline for the submission of bids.

C. Preparation of Bids

8. Language of Bid	8.1 The bid prepared by the Bidder, as well as all correspondence and documents relating to the bid exchanged by the Bidder and the Purchaser shall be written in the language specified in the Bid Data Sheet. Supporting documents and printed literature furnished by the Bidder may be in same language.
9. Documents Comprising the Bid	9.1 The bid prepared by the Bidder shall comprise the following components: (a) a Bid Form and a Price Schedule completed in accordance with ITB Clauses 10, 11, and 12; (b) documentary evidence established in accordance with ITB Clause 13 that the Bidder is eligible to bid and is qualified to perform the contract if its bid is accepted;

	(c) documentary evidence established in accordance with ITB Clause 14 that the goods and ancillary services to be supplied by the Bidder are eligible goods and services and conform to the bidding documents; and (d) bid security furnished in accordance with ITB Clause 15.
10. Bid Form	10.1 The Bidder shall complete the Bid Form and the appropriate Price Schedule furnished in the bidding documents, indicating the goods to be supplied, a brief description of the goods, and their country of origin, quantity, and prices.
11. Bid Prices	11.1 The Bidder shall indicate on the appropriate Price Schedule the unit prices (where applicable) and total bid price of the goods it proposes to supply under the contract. 11.2 Prices indicated on the Price Schedule shall be **delivered duty paid (DDP) prices**. 11.3 The Bidder's separation of price components in accordance with ITB Clause 11.2 above will be solely for the purpose of facilitating the comparison of bids by the Purchaser and will not in any way limit the Purchaser's right to contract on any of the terms offered. 11.4 Prices quoted by the Bidder shall be fixed during the Bidder's performance of the contract and not subject to variation on any account, unless otherwise specified in the Bid Data Sheet. A bid submitted with an **adjustable price quotation** will be treated as nonresponsive and will be rejected, pursuant to ITB Clause 24.
12. Bid Currencies	12.1 Prices shall be quoted in **Pak Rupees** unless otherwise specified in the Bid Data Sheet.
13. Documents Establishing Bidder's Eligibility and Qualification	13.1 Pursuant to ITB Clause 9, the Bidder shall furnish, as part of its bid, documents establishing the Bidder's eligibility to bid and its qualifications to perform the contract if its bid is accepted. 13.2 The documentary evidence of the Bidder's eligibility to bid shall establish to the Purchaser's satisfaction that the Bidder, at the time of submission of its bid, is eligible as defined under ITB Clause 2. 13.3 The documentary evidence of the Bidder's qualifications to perform the contract if its bid is accepted shall establish to the Purchaser's satisfaction: (a) that, in the case of a Bidder offering to supply goods under the contract which the Bidder did not manufacture or otherwise produce, the Bidder has been duly authorized by the goods' Manufacturer or producer to supply the in Pakistan; (b) that the Bidder has the financial, technical, and production capability necessary to perform the contract; (c) that, in the case of a Bidder not doing business within Pakistan, the Bidder is or will be (if awarded the contract) represented by an Agent in that country equipped, and able to carry out the Supplier's maintenance, repair, and spare parts-stocking obligations prescribed in the Conditions of Contract and/or Technical Specifications; and (d) That the Bidder meets the qualification criteria listed in the Bid Data Sheet.
14. Documents Establishing	14.1 Pursuant to ITB Clause 9, the Bidder shall furnish, as part of its bid, documents establishing the eligibility and conformity to the bidding

Goods' Eligibility and Conformity to Bidding Documents	documents of all goods and services which the Bidder proposes to supply under the contract. 14.2 The documentary evidence of the eligibility of the goods and services shall consist of a statement in the Price Schedule of the country of origin of the goods and services offered which shall be confirmed by a **certificate of origin** issued at the time of shipment. 14.3 The documentary evidence of conformity of the goods and services to the bidding documents may be in the form of literature, drawings, and data, and shall consist of: (a) a detailed description of the essential technical and performance characteristics of the goods; (b) a list giving full particulars, including available sources and current prices of spare parts, special tools, etc., necessary for the proper and continuing functioning of the goods for a period to be specified in the Bid Data Sheet, following commencement of the use of the goods by the Purchaser; and (c) an item-by-item commentary on the Purchaser's Technical Specifications demonstrating **substantial responsiveness** of the goods and services to those specifications, or a statement of deviations and exceptions to the provisions of the Technical Specifications. 14.4 For purposes of the commentary to be furnished pursuant to ITB Clause 14.3(c) above, the Bidder shall note that standards for workmanship, material, and equipment, as well as references to brand names or catalogue numbers designated by the 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.
15. Bid Security	15.1 Pursuant to ITB Clause 9, the Bidder shall furnish, as part of its bid, a bid security in the amount specified in the Bid Data Sheet 15.2 The bid security is required to protect the Purchaser against the risk of Bidder's conduct which would warrant the security's forfeiture, pursuant to ITB Clause 15.7. 15.3 The bid security shall be in Pak. Rupees and shall be in one of the following forms: (b) Bank call-deposit (CDR), Demand Draft (DD), Pay Order (PO) or Banker's cheque valid for thirty (30) days beyond the validity of bid. 15.4 Any bid not secured in accordance with ITB Clauses 15.1 and 15.3 will be rejected by the Purchaser as nonresponsive, pursuant to ITB Clause 24. 15.5 Unsuccessful bidders' bid security will be discharged or returned as promptly as possible but not later than thirty (30) days after the expiration of the period of bid validity prescribed by the Purchaser pursuant to ITB Clause 16. 15.6 The successful Bidder's bid security will be discharged upon the Bidder signing the contract, pursuant to ITB Clause 32, and furnishing the performance security, pursuant to ITB Clause 33. 15.7 The bid security may be forfeited:

	(a) if a Bidder withdraws its bid during the period of bid validity specified by the Bidder on the Bid Form; or (b) in the case of a successful Bidder, if the Bidder fails: (i) to sign the contract in accordance with ITB Clause 32; **or** (ii) to furnish performance security in accordance with ITB Clause 33.
16. Period of Validity of Bids	16.1 Bids shall remain valid for the period specified in the Bid Data Sheet after the date of bid opening prescribed by the Purchaser, pursuant to ITB Clause 19. A bid valid for a shorter period shall be rejected by the Purchaser as nonresponsive. 16.2 In exceptional circumstances, the Purchaser may solicit the Bidder's consent to an extension of the period of validity. The request and the responses thereto shall be made in writing (or by email). The bid security provided under ITB Clause 15 shall also be suitably extended. A Bidder may refuse the request without forfeiting its bid security. A Bidder granting the request will not be required nor permitted to modify its bid, except as provided in ITB Clause 16.3 16.3 In the case of fixed price contracts, if the award is delayed by a period exceeding sixty (60) days beyond the expiry of the initial bid validity, the contract price will be adjusted by a factor specified in the request for extension.
17. Format and Signing of Bid	17.1 The Bidder shall prepare an original and the number of copies of the bid indicated in the Bid Data Sheet, clearly marking each "ORIGINAL BID" and "COPY OF BID," as appropriate. In the event of any discrepancy between them, the original shall govern. 17.2 The original and the copy or copies of the bid shall be typed or written in indelible ink and shall be signed by the Bidder or a person or persons duly authorized to bind the Bidder to the contract. All pages of the bid, except for unamended printed literature, shall be initialed by the person or persons signing the bid. 17.3 Any interlineation, erasures, or overwriting shall be valid only if they are initialed by the person or persons signing the bid. 17.4 The Bidder shall furnish information as described in the Form of Bid on commissions or gratuities, if any, paid or to be paid to agents relating to this Bid, and to contract execution if the Bidder is awarded the contract.

D. Submission of Bids

18. Sealing and Marking of Bids	18.1 The Bidder shall seal the original and each copy of the bid in separate envelopes, duly marking the envelopes as "ORIGINAL" and "COPY." The envelopes shall then be sealed in an outer envelope. 18.2 The inner and outer envelopes shall: (a) be addressed to the Purchaser at the address given in the Bid Data Sheet; and (b) bear the title of procurement Activity indicated in the Bid Data Sheet, the Invitation for Bids (IFB) title and number indicated in the Bid Data Sheet, and a statement: "DO NOT OPEN BEFORE," to be completed with the time and the date specified in the Bid Data Sheet, pursuant to ITB Clause 2.2. 18.3 The inner envelopes shall also indicate the name and address of the Bidder to enable the bid to be returned unopened in case it is declared "late". 18.4 If the outer envelope is not sealed and marked as required by ITB Clause 18.2, the Purchaser will assume no responsibility for the bid's misplacement or premature opening.
19. Deadline for Submission of Bids	19.1 Bids must be received by the Purchaser at the address specified under ITB Clause 18.2 no later than the time and date specified in the Bid Data Sheet. 19.2 The Purchaser may, at its discretion, extend this deadline for the submission of bids by amending the bidding documents in accordance with ITB Clause 7, in which case all rights and obligations of the Purchaser and bidders previously subject to the deadline will thereafter be subject to the deadline as extended.
20. Late Bids	20.1 Any bid received by the Purchaser after the deadline for submission of bids prescribed by the Purchaser pursuant to ITB Clause 19 will be rejected and returned unopened to the Bidder.
21. Modification and Withdrawal of Bids	21.1 The Bidder may modify or withdraw its bid after the bid's submission, provided that written notice of the modification, including substitution or withdrawal of the bids, is received by the Purchaser prior to the deadline prescribed for submission of bids. 21.2 The Bidder's modification or withdrawal notice shall be prepared, sealed, marked, and dispatched in accordance with the provisions of ITB Clause 18. A withdrawal notice may also be sent by email, but followed by a signed confirmation copy, postmarked not later than the deadline for submission of bids. 21.3 No bid may be modified after the deadline for submission of bids. 21.4 No bid may be withdrawn in the interval between the deadline for submission of bids and the expiration of the period of bid validity specified by the Bidder on the Bid Form. Withdrawal of a bid during this interval may result in the Bidder's forfeiture of its bid security, pursuant to the ITB Clause 15.7.

E. Opening and Evaluation of Bids

22. Opening of Bids by the Purchaser	22.1 The Purchaser will open all bids in the presence of bidders' representatives who choose to attend, at the time, on the date, and at the place specified in the Bid Data Sheet. The bidders' representatives who are present shall sign an attendance sheet evidencing their presence. 22.2 The bidders' names, bid modifications or withdrawals, bid prices, discounts, and the presence or absence of requisite bid security and such other details as the Purchaser, at its discretion, may consider appropriate, will be announced at the opening. No bid shall be rejected at bid opening, except for late bids, which shall be returned unopened to the Bidder pursuant to ITB Clause 20. 22.3 Bids (and modifications sent pursuant to ITB Clause 21.2) that are not opened and read out at bid opening shall not be considered further for evaluation, irrespective of the circumstances. Withdrawn bids will be returned unopened to the bidders. 22.4 The Purchaser will prepare minutes of the bid opening.
23. Clarification of Bids	23.1 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.
24. Preliminary Examination	24.1 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. 24.2 Arithmetical errors will be rectified on the following basis. If there is a discrepancy between the unit price and the total price that is obtained by multiplying the unit price and quantity, the unit price shall prevail, and the total price shall be corrected. If the Supplier does not accept the correction of the errors, its bid will be rejected, and its bid security may be forfeited. If there is a discrepancy between words and figures, the amount in words will prevail. 24.3 The Purchaser may waive any minor informality, nonconformity, or irregularity in a bid which does not constitute a material deviation, provided such waiver does not prejudice or affect the relative ranking of any Bidder. 24.4 Prior to the detailed evaluation, pursuant to ITB Clause 25 the Purchaser will determine the substantial responsiveness of each bid to the bidding documents. For purposes of these Clauses, a substantially responsive bid is one which conforms to all the terms and conditions of the bidding documents without material deviations. Deviations from, or objections or reservations to critical provisions, **such as** those concerning **Bid Security** (ITB Clause 15), **Applicable Law** (GCC Clause 30), and **Taxes and Duties** (GCC Clause 32), will be deemed to be a material deviation. The Purchaser's determination of a bid's responsiveness is to be based on the contents of the bid itself without recourse to extrinsic evidence. 24.5 If a bid is not substantially responsive, it will be rejected by the Purchaser and may not subsequently be made responsive by the Bidder by correction of the nonconformity

25. Qualification & Evaluation of Bids	25.1 In the absence of **prequalification**, the Purchaser will determine to its satisfaction whether the Bidder is qualified to perform the contract satisfactorily, in accordance with the criteria listed in ITB Clause 13.3. 25.2 The determination will take into account the Bidder's financial, technical, and production capabilities. It will be based upon an examination of the documentary evidence of the Bidder's qualifications submitted by the Bidder, pursuant to ITB Clause 13.3, as well as such other information as the Purchaser deems necessary and appropriate. 25.3 The Purchaser will **technically evaluate** and compare the bids which have been determined to be substantially responsive, pursuant to ITB Clause 24, as per Technical Specifications required 25.4 The Purchaser's **financial evaluation** of a bid will be on delivered duty paid (DDP) price inclusive of prevailing taxes and duties.
Alternate	25.5 **Quality & Cost-based Selection:** The following merit point system for weighing evaluation factors can be applied **if specified** in the Bid Data Sheet. The number of points allocated to each factor shall be specified in the Bid Data Sheet. *[In the Bid Data Sheet, choose from the range of]* Price of the goods 60 to 90 Quality, technology and metallurgy 0 to 20 Performance and productivity 0 to 20 Standardization 0 to 20 Projected life-cycle cost 0 to 20 Operating and maintenance costs 0 to 20 Cost of spare parts and after-sales-service 0 to 20 Total 100 The bid scoring the highest number of points will be deemed to be the lowest evaluated bid.
26. Contacting the Purchaser	26.1 Subject to ITB Clause 23, no Bidder shall contact the Purchaser on any matter relating to its bid, from the time of the bid opening to the time evaluation report is made public i.e. 10 days before the contract is awarded. If the Bidder wishes to bring additional information or has grievance to the notice of the Purchaser, it should do so in writing. 26.2 Any effort by a Bidder to influence the Purchaser during bid evaluation, or bid comparison may result in the rejection of the Bidder's bid.

F. Award of Contract

28. Award Criteria	28.1 Subject to ITB Clause 30, the Purchaser will award the contract to the successful Bidder whose bid has been determined to be substantially responsive and has been determined to be the lowest evaluated bid, provided further that the Bidder is determined to be qualified to perform the contract satisfactorily.
29. Purchaser's Right to Vary Quantities at Time of Award	29.1 The Purchaser reserves the right at the time of contract award to increase or decrease, by the percentage indicated in the Bid Data Sheet, the quantity of goods and services originally specified in the Schedule of Requirements without any change in unit price or other terms and conditions.
30. Purchaser's Right to Accept or Reject All Bids	30.1 The Purchaser reserves the right to accept or reject all bids, and to annul the bidding process at any time prior to contract award, without thereby incurring any liability to the Bidder or bidders or any obligation to inform the Bidder or bidders of the grounds for the Purchaser's action.
31. Advance Acceptance of Tender	31.1 Prior to the expiration of the period of bid validity, the Purchaser will notify the successful Bidder in writing by registered letter or by email, to be confirmed in writing by registered letter, that its bid has been accepted. 31.2 The Advance Acceptance of Tender will constitute the formation of the Contract. 31.3 Upon the successful Bidder's furnishing of the performance security pursuant to ITB Clause 33, the Purchaser will promptly notify each unsuccessful Bidder and will discharge its bid security, pursuant to ITB Clause 15.
32. Signing of Contract	32.1 At the same time as 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. 32.2 Within seven (07) days of receipt of the Contract Form, the successful Bidder shall sign and date the contract and return it to the Purchaser.
33 Performance Security	33.1 Within fourteen (14) days of the receipt of Advance Acceptance of Tender from the Purchaser, the successful Bidder shall furnish the performance security in accordance with the Conditions of Contract, in the Performance Security Form provided in the bidding documents, or in another form acceptable to the Purchaser. 33.2 Failure of the successful Bidder to comply with the requirement of ITB Clause 32 or ITB Clause 33.1 shall constitute sufficient grounds for the annulment of the award and forfeiture of the bid security, in which event the Purchaser may make the award to the next lowest evaluated Bidder or call for new bids.

34. Corrupt or Fraudulent Practices	34.1 The Procuring Agency requires that Bidders, Suppliers, and Contractors observe the highest standard of ethics during the procurement and execution of contracts. For the purposes of this provision, the terms set forth below are defined as follows: (i) "corrupt practice" means the offering, giving, receiving or soliciting of anything of value to influence the action of a public official in the procurement process or in contract execution; and (ii) "fraudulent practice" means a misrepresentation of facts in order to influence a procurement process or the execution of a contract to the detriment of the Procuring Agency, (iii) "collusive practice" is an arrangement among bidders (prior to or after bid submission) designed to establish bid prices at artificial, non-competitive levels for any wrongful gains, and to deprive the Procuring Agency of the benefits of free and open competition; (b) The Procuring Agency will reject a proposal for award if it determines that the Bidder recommended for award has engaged in corrupt or fraudulent practices in competing for the contract in question; (c) The Procuring Agency will sanction a firm, in accordance with prevailing Blacklisting procedures under Punjab Procurement Rules 2014, if it at any time determines that the firm has engaged in corrupt or fraudulent practices in competing for, or in executing, a Bank-financed contract. 34.2 Furthermore, Bidders shall be aware of the provision stated in sub-clause 5.4 and sub-clause 24.1 of the General Conditions of Contract.

Part-I

Section II. Bid Data Sheet

The following specific data for the goods to be procured shall complement, supplement, or amend the provisions in the Instructions to Bidders (ITB) Part One. Whenever there is a conflict, the provisions herein shall prevail over those in ITB.

Introduction	
ITB 1.1	Name of Procuring Agency: Project Management Unit (PMU) Primary & Secondary Health Department, Government of the Punjab
ITB 1.1	Name of Project: Revamping of DHQ /THQ Hospitals in Punjab
ITB 1.1	Name of Contract: Supply of Goods
ITB 4.1	Name of Purchaser: Project Management Unit (PMU), Revamping of DHQ /THQ Hospitals in Punjab
ITB 6.1	For clarification purposes, the Employer's address is: PMU, Revamping of DHQ /THQ Hospitals in Punjab, 31 /E1,Shahra-e-Imam Hussain, Gulberg III, Lahore Requests for clarification shall be received by the Employer no Later than 8th September, 2020
ITB 8.1	Language of the bid – English

Bid Price and Currency	
ITB 11.2	The price quoted shall be Delivered Duty Paid at the following locations in accordance with the Schedule of Requirements including the delivery charges: Lahore City (Punjab)
ITB 11.5	The price shall be in Pak Rupees and shall be fixed.

Preparation and Submission of Bids	
ITB 13.2	a. Certificate of Incorporation of bidder's firm showing its location and the date of registration etc. b. NTN and GST Registration Certificate
ITB 13.3 (b)	Audited Balance Sheet or Bank Statement for the last 2 financial years (up to June 2020).
ITB 13.3 (d)	**Qualification requirements**. In addition to ITB 13.1, ITB 13.2, and ITB 13.3 (b), the potential bidder must also fulfill the following:- a) The Bidder must be a **Manufacturer** or an **Authorized Dealer/Distributor** for sales & service continuously from last one-year. b) **Technical Brochures** of Equipment quoted, mentioning its specifications, manufacture's model, product number, and country of origin. c) An **average annual sale** of **Rs. 2 million** (for Package-1) d) The bidder must have at least one local certified /authorized **repair and maintenance set-up**. e) Description of bidder's own **repair & maintenance set-up** with the location / addresses of workshops, mobile workshops (if any). f) **Authority Letter** from the Bidder Company authorizing the relevant person to represent the company. g) If an Agent submits bids on behalf of more than one Manufacturer, unless each such bid is accompanied by a separate Bid Form for each bid, and a bid security, when required, for each bid, and a valid authorized dealership certificate from the respective Manufacturer, all such bids will be rejected as nonresponsive.

<table>
<tr><td></td><td></td></tr>
<tr><td>ITB 14.3 (b)</td><td>A certificate from the dealer that all spare parts of the equipment to be supplied are easily available in Pakistan in the local market or from company owned outlets.</td></tr>
<tr><td>ITB 15.1</td><td>Amount of Bid Security:

<table><tr><th>Package</th><th>Item</th><th>Bid Security</th></tr><tr><td>LOT-I</td><td></td><td></td></tr></table>
Bids shall be in the prescribed format, sealed and accompanied by the Bid Security in the form of Call Deposit, Bank Draft, or Pay Order in favor of Project Director-PMU, Primary & Secondary Healthcare Department having its validity 90 days from the date of opening of bid.</td></tr>
<tr><td>ITB 16.1</td><td>Bid Validity Period: 90 days after the date of opening of bid.</td></tr>
<tr><td>ITB 17.1</td><td>Number of Copies: Original along with one Copy of the bid. Bids must be accompanied by unit price and total price.</td></tr>
<tr><td>ITB 18.2 (a)</td><td>Address for Bid Submission:

Procurement Specialist, Project Management Unit (PMU), Revamping of DHQ /THQ Hospitals in Punjab, 31 /E1,Shahra-e-Imam Hussain, Gulberg III, Lahore</td></tr>
<tr><td>ITB 18.2 (b)</td><td>IFB Title and Number:

<u>Package-1</u></td></tr>
</table>

ITB 19.1	Deadline for **Bid Submission**: **22th September 2020 at 11:00 a.m**
ITB 22.1	**Time, Date, and Place for Bid Opening:** **On 22th September 2020 at 11:30 a.m. at Office of Procurement Specialist,** Project Management Unit (PMU), Revamping of DHQ /THQ Hospitals in Punjab, 31 /E1,Shahra-e-Imam Hussain, Gulberg III, Lahore

Bid Evaluation	
ITB 25.3	Criteria for bid evaluation: Lowest Delivered Duty Paid (DDP) Total Price offered by the qualified responsive bidder.

Contract Award	
ITB 29.1	Percentage for quantity increase or decrease: 15 % of total contract value

Section III. Schedule of Requirements

The delivery schedule expressed as weeks stipulates hereafter a delivery date which is the date of delivery required.

TABLE 1 DELIVERY SCHEDULE

Package-1	**Location**	**Item**	**Qty**	**Delivery Period** from the date of Advance Acceptance of Tender
LOT-I	*PMU, Lahore*			**8-10 Weeks**

Part-I

Section IV. Technical Specifications

CRITERIA FOR TECHNICAL EVALUATION OF THE TENDER (For Sample specific items)

The quotation /bid who secure 65% marks will qualify for the competition.

Sr. No.	Parameter	Weight age
1	Business Volume	
2	Age of Company/Firm	
3	Financial strength of the vender	
4	H.R. Strength	
5	Relevant experience	
6	Sample	
TOTAL		**100%**

Package-1 LOT-I: GOODS

BROAD SPECIFICATIONS:

Part-I

Section V. Bidding Forms

Bid Submission Form

Date: _____

No: _____

To

The Project Director,

Project Management Unit,

Primary & Secondary Health Department

Government of the Punjab

31/E1, Shahra-e-Imam Hussain, Gulberg III, Lahore.

Having examined the bidding documents including Addenda Nos. *[insert numbers],* the receipt of which is hereby duly acknowledged, we, the undersigned, offer to supply and deliver *[description of goods and services]* in conformity with the said bidding documents for the sum of *[total bid amount in words and figures]* or such other sums as may be ascertained in accordance with the Schedule of Prices attached herewith and made part of this Bid.

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

If our Bid is accepted, we will obtain the **guarantee of a bank in a sum equivalent to 5% percent of the Contract Price** for the due performance of the Contract, in the form prescribed by the Purchaser.

We agree to abide by this Bid for a period of 90 days from the date fixed for Bid opening under Clause 22 of the Instructions to Bidders, and it shall remain binding upon us and may be accepted at any time before the expiration of that period.

Until a formal Contract is prepared and executed, this Bid, together with your written acceptance thereof and your Advance Acceptance of Tender, shall constitute a binding Contract between us.

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

Name and address of agent	Amount and Currency	Purpose of Commission or gratuity
_____	_____	_____
_____	_____	_____
_____	_____	_____

(if none, state "none")

We understand that you are not bound to accept the lowest or any bid you may receive.

Dated this _____ day of _____ 20_____.

_____ _____

[signature] *[in the capacity of]*

Duly authorized to sign Bid for and on behalf of _____

2. Manufacturer's Authorization Form

[See Clause 13.3 (a) of the Instructions to Bidders.]

To: *[name of the Purchaser]*

WHEREAS *[name of the Manufacturer]* who are established and reputable manufacturers of *[name and/or description of the goods]* having factories at *[address of factory]*

do hereby authorize *[name and address of Agent]* to submit a bid, and subsequently negotiate and sign the Contract with you against IFB No. *[Reference of the Invitation to Bid]* for the above goods manufactured by us.

We hereby extend our full guarantee and warranty as per Clause 15 of the General Conditions of Contract for the goods offered for supply by the above firm against this Invitation for Bids.

[signature for and on behalf of Manufacturer]

Note: This letter of authority should be on the letterhead of the Manufacturer and should be signed by a person competent and having the power of attorney to bind the Manufacturer. It should be included by the Bidder in its bid.

3. Price Schedules

Package 1: Blinds for Windows

Sr.	Item	Brand/Model/Origin	Qty	Unit Price (Rs.)	Total Amount (Rs.)
2					
				TOTAL AMOUNT (Rs.)	

Note:

1. In case of discrepancy between unit price and total, the unit price shall prevail.
2. The supplier has to provide the following free of cost:
   i. Technical and Operation Manual.
   ii. At site complete training of Purchaser's nominated staff regarding maintenance and operation of Goods.
   iii. Provide color picture/samples of all quoted items with detail specifications on company letter head and also provide brochures published by company/manufacturer(if available)
   iv. On site One year parts and labor warranty for all components.
   v. On site installation.

Part-II

Section I. Contract Forms

1. Contract Form

THIS AGREEMENT made the _____ day of _____ 20_____ between *[name of Purchaser]* (hereinafter called "the Purchaser") of the one part and *[name of Supplier]* of (hereinafter called "the Supplier") of the other part:

WHEREAS the Purchaser invited bids for certain goods and ancillary services, viz., *[brief description of goods and services]* and has accepted a bid by the Supplier for the supply of those goods and services in the sum of *[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 be deemed to form and be read and construed as part of this Agreement, viz.:
(a) the Bid Form and the Price Schedule submitted by the Bidder;
(b) the Schedule of Requirements;
(c) the Technical Specifications;
(d) the General Conditions of Contract;
(e) the Special Conditions of Contract; and
(f) the Purchaser's Advance Acceptance of Tender.

3. In consideration of the payments to be made by the Purchaser to the Supplier as hereinafter mentioned, the Supplier hereby covenants with the Purchaser to provide the goods and services and to remedy defects therein in conformity in all respects with the provisions of the Contract

4. The Purchaser hereby covenants to pay the Supplier in consideration of the provision of the goods and services and the remedying of defects therein, the Contract Price or such other sum as may become payable under the provisions of the contract at the times and in the manner prescribed by the contract.

IN WITNESS whereof the parties hereto have caused this Agreement to be executed in accordance with their respective laws the day and year first above written.

Signed, sealed, delivered by _____ the _____ (for the Purchaser)

Signed, sealed, delivered by _____ the _____ (for the Supplier

2. Performance Security Form

To:

The Project Director
Project Management Unit (PMU)
Revamping of DHQ /THQ Hospitals in Punjab
31/E1, Shahra-e-Imam Hussain, Gulberg III, Lahore.

WHEREAS *[name of Supplier]* (hereinafter called "the Supplier") has undertaken, in pursuance of Contract No. *[reference number of the contract]* dated _____ 20_____ to supply *[description of goods and services] (*hereinafter called "the Contract").

AND WHEREAS it has been stipulated by you in the said Contract that the Supplier shall furnish you with a bank guarantee by a reputable bank for the sum specified therein as security for compliance with the Supplier's performance obligations in accordance with the Contract.

AND WHEREAS we have agreed to give the Supplier a guarantee:

THEREFORE WE hereby affirm that we are Guarantors and responsible to you, on behalf of the Supplier, up to a total of *[amount of the guarantee in words and figures],* and we undertake to pay you, upon your first written demand declaring the Supplier to be in default under the Contract and without cavil or argument, any sum or sums within the limits of *[amount of guarantee]* as aforesaid, without your needing to prove or to show grounds or reasons for your demand or the sum specified therein.

This guarantee is valid until the _____ day of _____20_____.

Signature and seal of the Guarantors

_____
[name of bank or financial institution]

_____
[address]

_____

[date]

BID SECURITY (Bank Guarantee)

Security Executed on _____ (Date)

Name of Surety (Bank) with Address: _____

(Scheduled Bank in Pakistan)

Name of Principal (Bidder) with Address _____
_____

Penal Sum of Security Rupees. _____(Rs. _____) Bid Reference No. _____ KNOW ALL MEN BY THESE PRESENTS, that in pursuance of the terms of the Bid and at the request of the said Principal (Bidder) we, the Surety above named, are held and firmly bound unto _____ (hereinafter called the 'Employer') in the sum stated above for the payment of which sum well and truly to be made, we bind ourselves, our heirs, executors, administrators and successors, jointly and severally, firmly by these presents.

THE CONDITION OF THIS OBLIGATION IS SUCH, that whereas the Bidder has submitted the accompanying Bid dated _____ for Bid No. _____ for_____(Particulars of Bid) to the said Employer; and

WHEREAS, the Employer has required as a condition for considering said Bid that the Bidder furnishes a Bid Security in the above said sum from a Scheduled Bank in Pakistan or from a foreign bank duly counter-guaranteed by a Scheduled Bank in Pakistan, to the Employer, conditioned as under:

1. that the Bid Security shall remain in force up to and including the date---------- days after the deadline for validity of bids as stated in the Instructions to Bidders or as it may be extended by the Employer, notice of which extension(s) to the Surety is hereby waived;
2. that the Bid Security of unsuccessful Bidders will be returned by the Employer after expiry of its validity or upon signing of the Contract Agreement; and
3. That in the event of failure of the successful Bidder to execute the proposed Contract Agreement for such work and furnish the required Performance Security.

NOW THEREFORE, if the successful Bidder shall, within the period specified therefor, on the prescribed form presented to him for signature enter into a formal Contract with the said Employer in accordance with his Bid as accepted and furnish within--------- days of his being requested to do so, a Performance Security with good and sufficient surety, as may be required, upon the form prescribed by the said Employer for the faithful performance and proper fulfillment of the said Contract or in the event of non-withdrawal of the said Bid within the time specified for its validity then this obligation shall be void and of no effect, but otherwise to remain in full force and effect.

PROVIDED THAT the Surety shall forthwith pay the Employer (Procuring Agency) the said sum upon first written demand of the Employer (without cavil or argument) and without requiring the Employer to prove or to show grounds or reasons for such demand, notice of which shall be sent by the Employer by registered post duly addressed to the Surety at its address given above.

PROVIDED ALSO THAT the Employer shall be the sole and final judge for deciding whether the Principal (Bidder) has duly performed his obligations to sign the Contract Agreement and to furnish the requisite Performance Security within the time stated above, or has defaulted in fulfilling said

requirements and the Surety shall pay without objection the said sum upon demand from the Employer forthwith and without any reference to the Principal (Bidder) or any other person.

IN WITNESS WHEREOF, the above bounden Surety has executed the instrument under its seal on the date indicated above, the name and seal of the Surety being hereto affixed and these presents duly signed by its undersigned representative pursuant to authority of its governing body.

SURETY (Bank)

WITNESS: Signature_____

1. _____ Name_____

   _____ Title_____

   Corporate Secretary (Seal) Corporate Guarantor (Seal)

2. _____

   _____

   Name, Title & Address

Part-II

Section II. General Conditions of Contract

1 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) "The Goods" means all of the equipment, machinery, and/or other materials which the Supplier is required to supply to the Purchaser under the Contract.

(d) "The Services" means those services ancillary to the supply of the Goods, such as transportation and insurance, and any other incidental services, such as installation, commissioning, provision of technical assistance, training, and other such obligations of the Supplier covered under the Contract.

(e) "GCC" means the General Conditions of Contract contained in this section.

(f) "SCC" means the Special Conditions of Contract.

(g) "The Purchaser" means the organization purchasing the Goods, as named in SCC.

(h) "The Purchaser's country" is Islamic Republic of Pakistan.

(i) "The Supplier" means the individual or firm supplying the Goods and Services under this Contract.

(j) "The Project Site," where applicable, means the place or places named in SCC.

(k) "Day" means calendar day.

2. Application	2.1 These General Conditions shall apply to the extent that they are not superseded by provisions of other parts of the Contract.
3. Country of Origin	3.2 For purposes of this Clause, "origin" means the place where the Goods were mined, grown, or produced, or from which the Services are supplied. Goods are produced when, through manufacturing, processing, or substantial and major assembly of components, a commercially recognized new product results that is substantially different in basic characteristics or in purpose or utility from its components. 3.3 The origin of Goods and Services is distinct from the nationality of the Supplier.
4. Standards	4.1 The Goods supplied under this Contract shall conform to the standards mentioned in the Technical Specifications, and, when no applicable standard is mentioned, to the authoritative standards appropriate to the Goods' country of origin. Such standards shall be the latest issued by the concerned institution.
5. Use of Contract Documents and Information; Inspection and Audit by the Bank	5.1 The Supplier shall not, without the Purchaser's prior written consent, disclose the Contract, or any provision thereof, or any specification, plan, drawing, pattern, sample, or information furnished by or on behalf of the Purchaser in connection therewith, to any person other than a person employed by the Supplier in the performance of the Contract. Disclosure to any such employed person shall be made in confidence and shall extend only so far as may be necessary for purposes of such performance. 5.2 The Supplier shall not, without the Purchaser's prior written consent, make use of any document or information enumerated in GCC Clause 5.1 except for purposes of performing the Contract.

	5.3 Any document, other than the Contract itself, enumerated in GCC Clause 5.1 shall remain the property of the Purchaser and shall be returned (all copies) to the Purchaser on completion of the Supplier's performance under the Contract if so required by the Purchaser. 5.4 The Supplier shall permit the Procuring Agency to inspect the Supplier's accounts and records relating to the performance of the Supplier and to have them audited by auditors appointed by the Procuring Agency, if so required by the Procuring Agency.
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 Goods or any part thereof.
7. Performance Security	7.1 Within ten (10) 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 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 acceptable to the Purchaser and shall be in one of the following forms: (a) a bank guarantee or an irrevocable letter of credit issued by a reputable bank located in Pakistan, in the form provided in the bidding documents or another form 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 SCC.
8. Inspections and Tests	8.1 The Purchaser or its representative shall have the right to inspect and/or to test the Goods to confirm their conformity to the Contract specifications at no extra cost to the Purchaser. 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. 8.2 The inspections and tests may be conducted on the premises of the Supplier or its subcontractor(s), at point of delivery, and/or at the Goods' final destination. If conducted on the premises of the Supplier or its subcontractor(s), all reasonable facilities and assistance, including access to drawings and production data, shall be furnished to the inspectors at no charge to the Purchaser. 8.3 Should any inspected or tested Goods fail to conform to the Specifications, the Purchaser may reject the Goods, and the Supplier shall either replace the rejected Goods or make alterations necessary to meet specification requirements free of cost to the Purchaser. 8.4 The Purchaser's right to inspect, test and, where necessary, reject the Goods after the Goods' arrival in Pakistan shall in no way be limited or waived by reason of the Goods having previously been inspected, tested, and passed by the Purchaser or its representative prior to the Goods' shipment from the country of origin.

	8.5 Nothing in GCC Clause 8 shall in any way release the Supplier from any warranty or other obligations under this Contract.
9. Packing	9.1 The Supplier shall provide such packing of the Goods as is required to prevent their damage or deterioration during transit to their final destination, as indicated in the Contract. The packing shall be sufficient to withstand, without limitation, rough handling during transit and exposure to extreme temperatures, salt and precipitation during transit, and open storage. Packing case size and weights shall take into consideration, where appropriate, the remoteness of the Goods' final destination and the absence of heavy handling facilities at all points in transit. 9.2 The packing, marking, and documentation within and outside the packages shall comply strictly with such special requirements as shall be expressly provided for in the Contract, including additional requirements, if any, specified in SCC, and in any subsequent instructions ordered by the Purchaser.
10. Delivery and Documents	10.1 Delivery of the Goods shall be made by the Supplier in accordance with the terms specified in the Schedule of Requirements. The details of shipping and/or other documents to be furnished by the Supplier are specified in SCC. 10.2 Documents to be submitted by the Supplier are specified in SCC.
11. Insurance	11.1 The Goods supplied under the Contract shall be delivered duty paid (DDP) under which risk is transferred to the buyer after having been delivered; hence insurance coverage is seller's responsibility.
12. Transportation	12.1 The Supplier is required under the Contact to transport the Goods to a specified place of destination within the Purchaser's country, 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.
13. Incidental Services	13.1 The Supplier may be required to provide any or all of the following services, including additional services, if any, specified in SCC: (a) performance or supervision of on-site assembly and/or start-up of the supplied Goods; (b) furnishing of tools required for assembly and/or maintenance of the supplied Goods; (c) furnishing of a detailed operations and maintenance manual for each appropriate unit of the supplied Goods; (d) performance or supervision or maintenance and/or repair of the supplied Goods, for a period of time agreed by the parties, provided that this service shall not relieve the Supplier of any warranty obligations under this Contract; and (e) Training of the Purchaser's personnel, at the Supplier's plant and/or on-site, in assembly, start-up, operation, maintenance, and/or repair of the supplied Goods. 13.2 Prices charged by the Supplier for incidental services, if not included in the Contract Price for the Goods, shall be agreed upon in advance by the parties and shall not exceed the prevailing rates charged for other parties by the Supplier for similar services.

14. Spare Parts	14.1 As specified in SCC, the Supplier may be required to provide any or all of the following materials, notifications, and information pertaining to spare parts manufactured or distributed by the Supplier: (a) such spare parts as the Purchaser may elect to purchase from the Supplier, provided that this election shall not relieve the Supplier of any warranty obligations under the Contract; and (b) in the event of termination of production of the spare parts: (i) advance notification to the Purchaser of the pending termination, in sufficient time to permit the Purchaser to procure needed requirements; and (ii) Following such termination, furnishing at no cost to the Purchaser, the blueprints, drawings, and specifications of the spare parts, if requested.
15. Warranty	15.1 The Supplier warrants that the Goods supplied under the Contract are new, unused, of the most recent or current models and those they incorporate all recent improvements in design and materials unless provided otherwise in the Contract. The Supplier further warrants that all Goods supplied under this Contract shall have no defect, arising from design, materials, or workmanship (except when the design and/or material is required by the Purchaser's specifications) or from any act or omission of the Supplier, that may develop under normal use of the supplied Goods in the conditions prevailing in the country of final destination. 15.2 This warranty shall remain valid for twelve (12) months after the Goods, or any portion thereof as the case may be, have been delivered to and accepted at the final destination indicated in the Contract, or for eighteen (18) months after the date of shipment from the port or place of loading in the source country, whichever period concludes earlier, unless specified otherwise in SCC. 15.3 The Purchaser shall promptly notify the Supplier in writing of any claims arising under this warranty. 15.4 Upon receipt of such notice, the Supplier shall, within the period specified in SCC and with all reasonable speed, repair or replace the defective Goods or parts thereof, without costs to the Purchaser. 15.5 If the Supplier, having been notified, fails to remedy the defect(s) within the period specified in SCC, within a reasonable period, the Purchaser may proceed to take such remedial action as may be necessary, at the Supplier's risk and expense and without prejudice to any other rights which the Purchaser may have against the Supplier under the Contract.
16. Payment	16.1 The method and conditions of payment to be made to the Supplier under this Contract shall be specified in SCC. 16.2 The Supplier's request(s) for payment shall be made to the Purchaser in writing, accompanied by an invoice describing, as appropriate, the Goods delivered and Services performed, and by documents submitted pursuant to GCC Clause 10, and upon fulfillment of other obligations stipulated in the Contract. 16.3 Payments shall be made promptly by the Purchaser, but in no case later than thirty (30) days after submission of an invoice or claim by the Supplier. 16.4 The currency of payment is Pak. Rupees

17. Prices	17.1 Prices charged by the Supplier for Goods delivered and Services performed under the Contract shall not vary from the prices quoted by the Supplier in its bid, with the exception of any price adjustments authorized in SCC or in the Purchaser's request for bid validity extension, as the case may be.
18. Change Orders	18.1 The Purchaser may at any time, by a written order given to the Supplier pursuant to GCC Clause 31, make changes within the general scope of the Contract in any one or more of the following: (a) drawings, designs, or specifications, where Goods to be furnished under the Contract are to be specifically manufactured for the Purchaser; (b) the method of shipment or packing; (c) the place of delivery; and/or (d) the Services to be provided by the Supplier. 18.2 If any such change causes an increase or decrease in the cost of, or the time required for, the Supplier's performance of any provisions under the Contract, an equitable adjustment shall be made in the Contract Price or delivery schedule, or both, and the Contract shall accordingly be amended. Any claims by the Supplier for adjustment under this clause must be asserted within thirty (30) days from the date of the Supplier's receipt of the Purchaser's change order.
19. Contract Amendments	19.1 Subject to GCC Clause 18, no variation in or modification of the terms of the Contract shall be made except by written amendment signed by the parties.
20. Assignment	20.1 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.
21. Subcontracts	21.1 The Supplier shall notify the Purchaser in writing of all subcontracts awarded under this Contract if not already specified in the bid. Such notification, in the original bid or later, shall not relieve the Supplier from any liability or obligation under the Contract. 21.2 Subcontracts must comply with the provisions of GCC Clause 3.
22. Delays in the Supplier's Performance	22.1 Delivery of the Goods and performance of Services shall be made by the Supplier in accordance with the time schedule prescribed by the Purchaser in the Schedule of Requirements. 22.2 If at any time during performance of the Contract, the Supplier or its subcontractor(s) should encounter conditions impeding timely delivery of the Goods and performance of Services, the Supplier shall promptly notify the Purchaser in writing of the fact of the delay, its likely duration and its cause(s). As soon as practicable after receipt of the Supplier's notice, the Purchaser shall evaluate the situation and may at its discretion extend the Supplier's time for performance, with or without liquidated damages, in which case the extension shall be ratified by the parties by amendment of Contract. 22.3 Except as provided under GCC Clause 25, a delay by the Supplier in the performance of its delivery obligations shall render the Supplier liable to the imposition of liquidated damages pursuant to GCC Clause 23, unless an extension of time is agreed upon pursuant to GCC Clause 22.2 without the application of liquidated damages.

23. Liquidated Damages	23.1 Subject to GCC Clause 25, if the Supplier fails to deliver any or all of the Goods or to perform the Services within the period(s) specified in the Contract, the Purchaser shall, without prejudice to its other remedies under the Contract, deduct from the Contract Price, as liquidated damages, a sum equivalent to the percentage specified in SCC of the delivered price of the delayed Goods or unperformed Services for each week or part thereof of delay until actual delivery or performance, up to a maximum deduction of the percentage specified in SCC. Once the maximum is reached, the Purchaser may consider termination of the Contract pursuant to GCC Clause 24.
24. Termination for Default	24.1 The Purchaser, without prejudice to any other remedy for breach of Contract, by written notice of default sent to the Supplier, may terminate this Contract in whole or in part: (a) if the Supplier fails to deliver any or all of the Goods within the period(s) specified in the Contract, or within any extension thereof granted by the Purchaser pursuant to GCC Clause 22; or (b) if the Supplier fails to perform any other obligation(s) under the Contract. (c) if the Supplier, in the judgment of the Purchaser has engaged in corrupt or fraudulent practices in competing for or in executing the Contract. For the purpose of this clause: "corrupt practice" means the offering, giving, receiving or soliciting of anything of value to influence the action of a public official in the procurement process or in contract execution. "fraudulent practice" means a misrepresentation of facts in order to influence a procurement process or the execution of a contract to the detriment of the Procuring Agency, and includes collusive practice among Bidders (prior to or after bid submission) designed to establish bid prices at artificial non-competitive levels and to deprive the Procuring Agency of the benefits of free and open competition. 24.2 In the event the Purchaser terminates the Contract in whole or in part, pursuant to GCC Clause 24.1, the Purchaser may procure, upon such terms and in such manner as it deems appropriate, Goods or Services similar to those undelivered, and the Supplier shall be liable to the Purchaser for any excess costs for such similar Goods or Services. However, the Supplier shall continue performance of the Contract to the extent not terminated.
25. Force Majeure	25.1 Notwithstanding the provisions of GCC Clauses 22, 23, and 24, the Supplier shall not be liable for forfeiture of its performance security, liquidated damages, or termination for default if and to the extent that it's delay in performance or other failure to perform its obligations under the Contract is the result of an event of Force Majeure 25.2 For purposes of this clause, "Force Majeure" means an event beyond the control of the Supplier and not involving the Supplier's fault or negligence and not foreseeable. Such events may include, but are not restricted to, acts of the Purchaser in its sovereign capacity, wars or revolutions, fires, floods, epidemics, quarantine restrictions, and freight embargoes. 25.3 If a Force Majeure situation arises, the Supplier shall promptly notify the Purchaser in writing of such condition and the cause thereof.

	Unless otherwise directed by the Purchaser in writing, the Supplier shall continue to perform its obligations under the Contract as far as is reasonably practical, and shall seek all reasonable alternative means for performance not prevented by the Force Majeure event
26. Termination for Insolvency	26.1 The Purchaser may at any time terminate the Contract by giving written notice to the Supplier if the Supplier becomes bankrupt or otherwise insolvent. In this event, termination will be without compensation to the Supplier, provided that such termination will not prejudice or affect any right of action or remedy which has accrued or will accrue thereafter to the Purchaser.
27. Termination for Convenience	27.1 The Purchaser, by written notice sent to the Supplier, may terminate the Contract, in whole or in part, at any time for its convenience. The notice of termination shall specify that termination is for the Purchaser's convenience, the extent to which performance of the Supplier under the Contract is terminated, and the date upon which such termination becomes effective. 27.2 The Goods that are complete and ready for shipment within thirty (30) days after the Supplier's receipt of notice of termination shall be accepted by the Purchaser at the Contract terms and prices. For the remaining Goods, the Purchaser may elect: (a) to have any portion completed and delivered at the Contract terms and prices; and/or (b) to cancel the remainder and pay to the Supplier an agreed amount for partially completed Goods and Services and for materials and parts previously procured by the Supplier.
28. Resolution of Disputes	28.1 The Purchaser and the Supplier shall make every effort to resolve amicably by direct informal negotiation any disagreement or dispute arising between them under or in connection with the Contract. 28.2 If, after thirty (30) days from the commencement of such informal negotiations, the Purchaser and the Supplier have been unable to resolve amicably a Contract dispute, either party may require that the dispute be referred for resolution to the formal mechanisms specified in SCC. These mechanisms may include, but are not restricted to, conciliation mediated by a third party, adjudication in an agreed and/or arbitration.
29. Governing Language	29.1 The Contract shall be written in the language specified in SCC. Subject to GCC Clause 30, the version of the Contract written in the specified language shall govern its interpretation. All correspondence and other documents pertaining to the Contract which are exchanged by the parties shall be written in the same language.
30. Applicable Law	30.1 The Contract hall be interpreted in accordance with the laws of Islamic Republic of Pakistan.
31. Notices	31.1 Any notice given by one party to the other pursuant to this Contract shall be sent to the other party in writing or by fax and confirmed in writing to the other party's address specified in SCC. 31.2 A notice shall be effective when delivered or on the notice's effective date, whichever is later.

32. Taxes and Duties	32.1 Supplier shall be entirely responsible for all taxes, duties, license fees, etc., incurred until delivery of the contracted Goods to the Purchaser.

Part-II

Section III. Special Conditions of Contract

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

1. Definitions (GCC Clause 1)

GCC 1.1 (g)—The Purchaser is: Procurement Specialist, Project Management Unit (PMU), Revamping of DHQ/THQ Hospitals in Punjab, Primary & Secondary Health Department, Government of the Punjab 31-E/1, Shahra-e-Imam Hussain, Gulberg-III, Lahore.

GCC 1.1 (h)—The Purchaser's country is: Islamic Republic of Pakistan

GCC 1.1 (i)—The Supplier is:

GCC 1.1 (j)—The Project Site is: Lahore City (Punjab).

2. Country of Origin (GCC Clause 3)

3. Performance Security (GCC Clause 7)

GCC 7.1—The amount of performance security, as a percentage of the Contract Price, shall be 5% (Five per cent of the contract price) in the shape of non recourse, irrevocable and unconditional bank guarantee from scheduled bank of Pakistan on the prescribed format attached with the bidding document.

4. Inspections and Tests (GCC Clause 8)

GCC 8.6—

Inspection and tests prior to delivery of goods and at final acceptance are:-

i) For being Brand New, bearing relevant reference numbers of the equipment (Certificate from supplier)

ii) For Physical Fitness having No Damages (Certificate from supplier)

iii) For the Country of Origin as quoted by the Supplier (Certificate from manufacturer)

iv) For conformance to specifications and performance parameters, through Prior to delivery inspection (Inspection Report by PMU)

v) For successful operation at site after complete installation, testing and commissioning of the equipment (Installation, Testing and Commissioning Report by PMU)

5. Delivery and Documents (GCC Clause 10)

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

(i) Copies of the Supplier's invoice showing Goods' description, quantity, unit price, and total amount;

(ii) Original and two copies of the usual transport document (for example, a negotiable bill of lading, a non-negotiable sea waybill, an inland waterway document, an air waybill, a railway consignment note, a road consignment note, or a multimodal transport document) which the buyer may require to take the goods;

(iii) Copies of the packing list identifying contents of each package;

(iv) Insurance Certificate;

(v) Manufacturer's or Supplier's Valid Warranty Certificate;

(vi) Inspection Certificate issued by the Nominated Inspection Agency (if any), and the Supplier's Factory Inspection Report; and

(vii) Certificate of Origin.

(viii) The above documents would be required even if the equipment has already been imported and is available with the supplier ex-stock

6. Insurance (GCC Clause 11)

GCC 11.1— The Goods supplied under the Contract shall be Delivered Duty Paid (DDP) under which risk is transferred to the Buyer after having been delivered. Hence insurance coverage is seller's responsibility. Since the Insurance is seller's responsibility they may arrange appropriate coverage.

7. Incidental Services (GCC Clause 13)

GCC 13.1—Incidental services to be provided are:

A) At site complete training of Purchaser's nominated staff regarding maintenance and operation of Goods.

B) At site preventive maintenance on quarterly basis by the bidder's qualified staff for one year, starting from final acceptance of goods.

The rate must include cost for all kinds of labor, inputs and material required for above, and all applicable government taxes and levies. In case a separate rate is not provided by the bidder for the above items, it shall be deemed to have been covered in the overall quoted cost.

8. Warranty (GCC Clause 15)

GCC 15.2—In accordance with the provisions, the warranty period shall be 2000 hours of operation or 12 months (parts and labor warranty) from date of Handing Over (Final Acceptance) of the Goods whichever occurs earlier. The Supplier shall, in addition, comply with the performance and/or consumption guarantees specified under the Contract. If, for reasons attributable to the Supplier, these guarantees are not attained in whole or in part, the Supplier shall, at its discretion, either:

(a) Make such changes, modifications, and/or additions to the Goods or any part thereof as may be necessary in order to attain the contractual guarantees specified in the Contract at its own cost and expense and to carry out further performance tests in accordance with SCC 4,

or

(b) Pay liquidated damages to the Purchaser with respect to the failure to meet the contractual guarantees. The rate of these liquidated damages shall be 0.1 % of the contract price per day. The maximum amount of liquidated damages for the whole of the goods or part thereof shall be 5% of the contract price.

or

(c) Replacement of the whole unit at site including transportation, installation, testing & commissioning etc in case of major defect at his own cost.

GCC 15.4 & 15.5—the period for correction of defects in the warranty period is 72 hours.

9. Payment (GCC Clause 16)

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

Payment for Goods supplied:

Payment shall be made in Pak. Rupees in the following manner:

(i) Payment against Delivered Goods: Upon submission of claim, the supplier shall be paid within thirty (30) days of receipt of the Goods at site after performing the requisite inspection and tests as mentioned in SCC 4.

12. Prices (GCC Clause 17)

GCC 17.1—Prices shall be: Fixed.

13. Liquidated Damages (GCC Clause 23)

GCC 23.1—Applicable rate: 0.1 % of contract price per day

Maximum deduction: 5 % of contract price

14. Resolution of Disputes (GCC Clause 28)

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

In the case of a dispute between the Purchaser and the Supplier, the dispute shall be referred to adjudication or arbitration in accordance with the Pakistan Arbitration Act, 1940.

15. Governing Language (GCC Clause 29)

GCC 29.1—The Governing Language shall be: English.

16. Applicable Law (GCC Clause 30)

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

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

17. Notices (GCC Clause 31)

GCC 31.1—Purchaser's address for notice purposes – Office of Project Director, Project Management Unit (PMU), Revamping of DHQ /THQ Hospitals in Punjab, Primary & Secondary Health Department, Government of Punjab, 31/E1, Shahra-e-Imam Hussain, Gulberg III, Lahore.

—Supplier's address for notice purposes:

PROJECT MANAGEMENT UNIT (PMU)

REVAMPING OF DHQ /THQ HOSPITALS IN PUNJAB

B I D D I N G D O C U M E N T

Project Management Unit

Primary & Secondary Healthcare Department

GOVERNMENT OF THE PUNJAB

September 2020

Invitation for Bids

Dated: 4th Sept, 2020

1. The Project Management Unit (PMU) has received budget from Government of Punjab towards the cost of Revamping of DHQ /THQ Hospitals in Punjab. It is intended that part of the proceeds of this budget will be applied to eligible payments under the contract for supply of following items:

Package -1	Item	Qty	Bid Security

2. The PMU now invites sealed bids from eligible bidders, Manufacturers, authorized Sales & Service Dealers for the supply of above mentioned items.

3. Bidding shall be conducted through Open Competitive Bidding (Single Stage-Two Envelope) procedures specified in the Punjab Procurement Rules PPRA 2014 (amended Jan 2016), and is open to all eligible bidders as defined in the bidding document

4. Interested eligible bidders may obtain bidding documents and further information from the **Office** of **Procurement Specialist,** Project Management Unit, Revamping of DHQ /THQ Hospitals, 31/E1, Shahra-e-Imam Hussain, Gulberg III, Lahore or download from website: www.pshealth.punjab.gov.pk

5. The provisions in the Instructions to Bidders and in the General Conditions of Contract are the provisions of the Bidding Documents.

6. Sealed Bids must be delivered to the above office **on or before 11:00 a.m. on 22th September, 2020** and must be accompanied by a **Bid Security as mentioned above** in the form of CDR, Pay Order, Demand Draft, or Banker's Cheque from a Scheduled Bank of Pakistan.

7. **Bids will be opened in the presence of bidders' representatives who choose to attend at 11:30 a.m.** in the Office of **Procurement Specialist,** Project Management Unit, 31/E1, Shahra-e-Imam Hussain, Gulberg III, Lahore **on the same date.**

8. The bidders are requested to give their best and final prices as no negotiations are expected.

9. Taxes will be deducted as per applicable government rules. NTN and Sales Tax registration certificate must be provided.

10. For obtaining any further information or clarifications, please contact the person named below:

Procurement Specialist
Project Management Unit (PMU)
Revamping of DHQ /THQ Hospitals in Punjab
Primary & Secondary Health Department
Government of the Punjab
31-E/1, Shahra-e-Imam Hussain, Gulberg-III, Lahore
Tel: 042-99231202
Website: www.pshealth.punjab.gov.pk
E-mail: procurement.pmu.psh@gmail.com

Table of Contents

Part-I

Section I. Instructions to Bidders

A. Introduction

1. Source of Funds

1.1 The Procuring Agency named in the Bid Data Sheet has received budget from the Government of Punjab. The Procuring Agency intends to apply a portion of the proceeds of this budget to eligible payments under the contract for which this Invitation for Bids is issued

2. Eligible Bidders

2.1 This Invitation for Bids is open to all suppliers, except as provided hereinafter.

2.2 Bidders should not be associated, or have been associated in the past, directly or indirectly, with a firm or any of its affiliates which have been engaged by the Procuring Agency to provide consulting services for the preparation of the design, specifications, and other documents to be used for the procurement of the goods to be purchased under this Invitation for Bids.

2.3 Government-owned enterprises may participate only if they are legally and financially autonomous, if they operate under commercial law, and if they are not a dependent agency of the Government.

2.4 Bidders shall not be under a declaration of blacklisting by any Government department or Punjab Procurement Regulatory Authority (PPRA).

3. Eligible Goods and Services

3.1 All goods and related services to be supplied under the contract shall have their origin in eligible source countries, defined in the *Bid Data Sheet (BDS)*, and all expenditures made under the contract will be limited to such goods and services.

3.2 For purposes of this clause, "origin" means the place where the goods are mined, grown, or produced, or the place from which the related services are supplied. Goods are produced when, through manufacturing, processing, or substantial and major assembly of components, a commercially-recognized product results that is substantially different in basic characteristics or in purpose or utility from its components.

3.3 The origin of goods and services is distinct from the nationality of the Bidder.

4. Cost of Bidding

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

B. The Bidding Documents

5. Content of Bidding Documents

5.1 The goods required, bidding procedures, and contract terms are prescribed in the bidding documents. In addition to the Invitation for Bids, the bidding documents include:

(a) Instructions to Bidders (ITB)

(b) Bid Data Sheet

(c) Schedule of Requirements

(d) Technical Specifications

(e) Bid Submission Form

(f) Manufacturer's Authorization Form

(g) Price Schedules

(h) Contract Form

(i) Performance Security Form

(j) General Conditions of Contract (GCC)

(k) Special Conditions of Contract (SCC)

5.2 The Bidder is expected to examine all instructions, forms, terms, and specifications in the bidding documents. Failure to furnish all information required by the bidding documents or to submit a bid not substantially responsive to the bidding documents in every respect will be at the Bidder's risk and may result in the rejection of its bid.

6. Clarification of Bidding Documents

6.1 A prospective Bidder requiring any clarification of the bidding documents may notify the Purchaser in writing or by email at the Purchaser's address indicated in ITB Clause 19.1. The Purchaser will respond in writing to any request for clarification of the bidding documents which it receives no later than three (3) days prior to the deadline for the submission of bids prescribed in the Bid Data Sheet. Written copies of the Purchaser's response (including an explanation of the query but without identifying the source of inquiry) will be sent to all prospective bidders that have received the bidding documents

7. Amendment of Bidding Documents

7.1 At any time prior to the deadline for submission of bids, the Purchaser, for any reason, whether at its own initiative or in response to a clarification requested by a prospective Bidder, may modify the bidding documents by amendment.

7.2 All prospective bidders that have received the bidding documents will be notified of the amendment in writing or by email, and will be bidding on them.

7.3 In order to allow prospective bidders reasonable time in which to take the amendment into account in preparing their bids, the Purchaser, at its discretion, may extend the deadline for the submission of bids.

C. Preparation of Bids

8. Language of Bid

8.1 The bid prepared by the Bidder, as well as all correspondence and documents relating to the bid exchanged by the Bidder and the Purchaser shall be written in the language specified in the Bid Data Sheet. Supporting documents and printed literature furnished by the Bidder may be in same language.

9. Documents Comprising the Bid

9.1 The bid prepared by the Bidder shall comprise the following components:

(a) a Bid Form and a Price Schedule completed in accordance with ITB Clauses 10, 11, and 12;

(b) documentary evidence established in accordance with ITB Clause 13 that the Bidder is eligible to bid and is qualified to perform the contract if its bid is accepted;

(c) documentary evidence established in accordance with ITB Clause 14 that the goods and ancillary services to be supplied by the Bidder are eligible goods and services and conform to the bidding documents; and

(d) bid security furnished in accordance with ITB Clause 15.

10. Bid Form

10.1 The Bidder shall complete the Bid Form and the appropriate Price Schedule furnished in the bidding documents, indicating the goods to be supplied, a brief description of the goods, and their country of origin, quantity, and prices.

11. Bid Prices

11.1 The Bidder shall indicate on the appropriate Price Schedule the unit prices (where applicable) and total bid price of the goods it proposes to supply under the contract.

11.2 Prices indicated on the Price Schedule shall be **delivered duty paid (DDP) prices**.

11.3 The Bidder's separation of price components in accordance with ITB Clause 11.2 above will be solely for the purpose of facilitating the comparison of bids by the Purchaser and will not in any way limit the Purchaser's right to contract on any of the terms offered.

11.4 Prices quoted by the Bidder shall be fixed during the Bidder's performance of the contract and not subject to variation on any account, unless otherwise specified in the Bid Data Sheet. A bid submitted with an **adjustable price quotation** will be treated as nonresponsive and will be rejected, pursuant to ITB Clause 24.

12. Bid Currencies

12.1 Prices shall be quoted in **Pak Rupees** unless otherwise specified in the Bid Data Sheet.

13. Documents Establishing Bidder's Eligibility and Qualification

13.1 Pursuant to ITB Clause 9, the Bidder shall furnish, as part of its bid, documents establishing the Bidder's eligibility to bid and its qualifications to perform the contract if its bid is accepted.

13.2 The documentary evidence of the Bidder's eligibility to bid shall establish to the Purchaser's satisfaction that the Bidder, at the time of submission of its bid, is eligible as defined under ITB Clause 2.

13.3 The documentary evidence of the Bidder's qualifications to perform the contract if its bid is accepted shall establish to the Purchaser's satisfaction:

(a) that, in the case of a Bidder offering to supply goods under the contract which the Bidder did not manufacture or otherwise produce, the Bidder has been duly authorized by the goods' Manufacturer or producer to supply the in Pakistan;

(b) that the Bidder has the financial, technical, and production capability necessary to perform the contract;

(c) that, in the case of a Bidder not doing business within Pakistan, the Bidder is or will be (if awarded the contract) represented by an Agent in that country equipped, and able to carry out the Supplier's maintenance, repair, and spare parts-stocking obligations prescribed in the Conditions of Contract and/or Technical Specifications; and

(d) That the Bidder meets the qualification criteria listed in the Bid Data Sheet.

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

14.1 Pursuant to ITB Clause 9, the Bidder shall furnish, as part of its bid, documents establishing the eligibility and conformity to the bidding documents of all goods and services which the Bidder proposes to supply under the contract.

14.2 The documentary evidence of the eligibility of the goods and services shall consist of a statement in the Price Schedule of the country of origin of the goods and services offered which shall be confirmed by a **certificate of origin** issued at the time of shipment.

14.3 The documentary evidence of conformity of the goods and services to the bidding documents may be in the form of literature, drawings, and data, and shall consist of:

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

(b) a list giving full particulars, including available sources and current prices of spare parts, special tools, etc., necessary for the proper and continuing functioning of the goods for a period to be specified in the Bid Data Sheet, following commencement of the use of the goods by the Purchaser; and

(c) an item-by-item commentary on the Purchaser's Technical Specifications demonstrating **substantial responsiveness** of the goods and services to those specifications, or a statement of deviations and exceptions to the provisions of the Technical Specifications.

14.4 For purposes of the commentary to be furnished pursuant to ITB Clause 14.3(c) above, the Bidder shall note that standards for workmanship, material, and equipment, as well as references to brand names or catalogue numbers designated by the 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.

15. Bid Security

15.1 Pursuant to ITB Clause 9, the Bidder shall furnish, as part of its bid, a bid security in the amount specified in the Bid Data Sheet

15.2 The bid security is required to protect the Purchaser against the risk of Bidder's conduct which would warrant the security's forfeiture, pursuant to ITB Clause 15.7.

15.3 The bid security shall be in Pak. Rupees and shall be in one of the following forms:

(c) Bank call-deposit (CDR), Demand Draft (DD), Pay Order (PO) or Banker's cheque valid for thirty (30) days beyond the validity of bid.

15.4 Any bid not secured in accordance with ITB Clauses 15.1 and 15.3 will be rejected by the Purchaser as nonresponsive, pursuant to ITB Clause 24.

15.5 Unsuccessful bidders' bid security will be discharged or returned as promptly as possible but not later than thirty (30) days after the expiration of the period of bid validity prescribed by the Purchaser pursuant to ITB Clause 16.

15.6 The successful Bidder's bid security will be discharged upon the Bidder signing the contract, pursuant to ITB Clause 32, and furnishing the performance security, pursuant to ITB Clause 33.

15.7 The bid security may be forfeited:

(a) if a Bidder withdraws its bid during the period of bid validity specified by the Bidder on the Bid Form; or

(b) in the case of a successful Bidder, if the Bidder fails:

(i) to sign the contract in accordance with ITB Clause 32;

or

(ii) to furnish performance security in accordance with ITB Clause 33.

16. Period of Validity of Bids

16.1 Bids shall remain valid for the period specified in the Bid Data Sheet after the date of bid opening prescribed by the Purchaser, pursuant to ITB Clause 19. A bid valid for a shorter period shall be rejected by the Purchaser as nonresponsive.

16.2 In exceptional circumstances, the Purchaser may solicit the Bidder's consent to an extension of the period of validity. The request and the responses thereto shall be made in writing (or by email). The bid security provided under ITB Clause 15 shall also be suitably extended. A Bidder may refuse the request without forfeiting its bid security. A Bidder granting the request will not be required nor permitted to modify its bid, except as provided in ITB Clause 16.3

16.3 In the case of fixed price contracts, if the award is delayed by a period exceeding sixty (60) days beyond the expiry of the initial bid validity,

the contract price will be adjusted by a factor specified in the request for extension.

17. Format and Signing of Bid

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

17.2 The original and the copy or copies of the bid shall be typed or written in indelible ink and shall be signed by the Bidder or a person or persons duly authorized to bind the Bidder to the contract. All pages of the bid, except for unamended printed literature, shall be initialed by the person or persons signing the bid.

17.3 Any interlineation, erasures, or overwriting shall be valid only if they are initialed by the person or persons signing the bid.

17.4 The Bidder shall furnish information as described in the Form of Bid on commissions or gratuities, if any, paid or to be paid to agents relating to this Bid, and to contract execution if the Bidder is awarded the contract.

D. Submission of Bids

18. Sealing and Marking of Bids

18.1 The Bidder shall seal the original and each copy of the bid in separate envelopes, duly marking the envelopes as "ORIGINAL" and "COPY." The envelopes shall then be sealed in an outer envelope.

18.2 The inner and outer envelopes shall:

(a) be addressed to the Purchaser at the address given in the Bid Data Sheet; and

(b) bear the title of procurement Activity indicated in the Bid Data Sheet, the Invitation for Bids (IFB) title and number indicated in the Bid Data Sheet, and a statement: "DO NOT OPEN BEFORE," to be completed with the time and the date specified in the Bid Data Sheet, pursuant to ITB Clause 2.2.

18.3 The inner envelopes shall also indicate the name and address of the Bidder to enable the bid to be returned unopened in case it is declared "late".

18.4 If the outer envelope is not sealed and marked as required by ITB Clause 18.2, the Purchaser will assume no responsibility for the bid's misplacement or premature opening.

19. Deadline for Submission of Bids

19.1 Bids must be received by the Purchaser at the address specified under ITB Clause 18.2 no later than the time and date specified in the Bid Data Sheet.

19.2 The Purchaser may, at its discretion, extend this deadline for the submission of bids by amending the bidding documents in accordance with ITB Clause 7, in which case all rights and obligations of the Purchaser and bidders previously subject to the deadline will thereafter be subject to the deadline as extended.

20. Late Bids

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

21. Modification and Withdrawal of Bids

21.1 The Bidder may modify or withdraw its bid after the bid's submission, provided that written notice of the modification, including substitution or withdrawal of the bids, is received by the Purchaser prior to the deadline prescribed for submission of bids.

21.2 The Bidder's modification or withdrawal notice shall be prepared, sealed, marked, and dispatched in accordance with the provisions of ITB Clause 18. A withdrawal notice may also be sent by email, but followed by a signed confirmation copy, postmarked not later than the deadline for submission of bids.

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

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

E. Opening and Evaluation of Bids

22. Opening of Bids by the Purchaser

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

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

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

22.4 The Purchaser will prepare minutes of the bid opening.

23. Clarification of Bids

23.1 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.

24. Preliminary Examination

24.1 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.

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

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

24.4 Prior to the detailed evaluation, pursuant to ITB Clause 25 the Purchaser will determine the substantial responsiveness of each bid to the bidding documents. For purposes of these Clauses, a substantially responsive bid is one which conforms to all the terms and conditions of the bidding documents without material deviations. Deviations from, or objections or reservations to critical provisions, **such as** those concerning **Bid Security** (ITB Clause 15), **Applicable Law** (GCC Clause 30), and **Taxes and Duties** (GCC Clause 32), will be deemed to be a material deviation. The Purchaser's determination of a bid's responsiveness is to be based on the contents of the bid itself without recourse to extrinsic evidence.

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

25. Qualification & Evaluation of Bids

25.1 In the absence of **prequalification**, the Purchaser will determine to its satisfaction whether the Bidder is qualified to perform the contract satisfactorily, in accordance with the criteria listed in ITB Clause 13.3.

25.2 The determination will take into account the Bidder's financial, technical, and production capabilities. It will be based upon an examination of the documentary evidence of the Bidder's qualifications submitted by the Bidder, pursuant to ITB Clause 13.3, as well as such other information as the Purchaser deems necessary and appropriate.

25.3 The Purchaser will **technically evaluate** and compare the bids which have been determined to be substantially responsive, pursuant to ITB Clause 24, as per Technical Specifications required

25.4 The Purchaser's **financial evaluation** of a bid will be on delivered duty paid (DDP) price inclusive of prevailing taxes and duties.

Alternate

25.5 **Quality & Cost-based Selection:**

The following merit point system for weighing evaluation factors can be applied **if specified** in the Bid Data Sheet. The number of points allocated to each factor shall be specified in the Bid Data Sheet.

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

Price of the goods	60 to 90
Quality, technology and metallurgy	0 to 20
Performance and productivity	0 to 20
Standardization	0 to 20
Projected life-cycle cost	0 to 20
Operating and maintenance costs	0 to 20
Cost of spare parts and after-sales-service	0 to 20
Total	100

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

26. Contacting the Purchaser

26.1 Subject to ITB Clause 23, no Bidder shall contact the Purchaser on any matter relating to its bid, from the time of the bid opening to the time evaluation report is made public i.e. 10 days before the contract is awarded. If the Bidder wishes to bring additional information or has grievance to the notice of the Purchaser, it should do so in writing.

26.2 Any effort by a Bidder to influence the Purchaser during bid evaluation, or bid comparison may result in the rejection of the Bidder's bid.

F. Award of Contract

28. Award Criteria

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

29. Purchaser's Right to Vary Quantities at Time of Award

29.1 The Purchaser reserves the right at the time of contract award to increase or decrease, by the percentage indicated in the Bid Data Sheet, the quantity of goods and services originally specified in the Schedule of Requirements without any change in unit price or other terms and conditions.

30. Purchaser's Right to Accept or Reject All Bids

30.1 The Purchaser reserves the right to accept or reject all bids, and to annul the bidding process at any time prior to contract award, without thereby incurring any liability to the Bidder or bidders or any obligation to inform the Bidder or bidders of the grounds for the Purchaser's action.

31. Advance Acceptance of Tender

31.1 Prior to the expiration of the period of bid validity, the Purchaser will notify the successful Bidder in writing by registered letter or by email, to be confirmed in writing by registered letter, that its bid has been accepted.

31.2 The Advance Acceptance of Tender will constitute the formation of the Contract.

31.3 Upon the successful Bidder's furnishing of the performance security pursuant to ITB Clause 33, the Purchaser will promptly notify each unsuccessful Bidder and will discharge its bid security, pursuant to ITB Clause 15.

32. Signing of Contract

32.1 At the same time as 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.

32.2 Within seven (07) days of receipt of the Contract Form, the successful Bidder shall sign and date the contract and return it to the Purchaser.

33 Performance Security

33.1 Within fourteen (14) days of the receipt of Advance Acceptance of Tender from the Purchaser, the successful Bidder shall furnish the performance security in accordance with the Conditions of Contract, in the Performance Security Form provided in the bidding documents, or in another form acceptable to the Purchaser.

33.2 Failure of the successful Bidder to comply with the requirement of ITB Clause 32 or ITB Clause 33.1 shall constitute sufficient grounds for the annulment of the award and forfeiture of the bid security, in which event the Purchaser may make the award to the next lowest evaluated Bidder or call for new bids.

34. Corrupt or Fraudulent Practices

34.1 The Procuring Agency requires that Bidders, Suppliers, and Contractors observe the highest standard of ethics during the procurement and execution of contracts. For the purposes of this provision, the terms set forth below are defined as follows:

(i) "corrupt practice" means the offering, giving, receiving or soliciting of anything of value to

influence the action of a public official in the procurement process or in contract execution; and

(ii) "fraudulent practice" means a misrepresentation of facts in order to influence a procurement process or the execution of a contract to the detriment of the Procuring Agency,

(iii) "collusive practice" is an arrangement among bidders (prior to or after bid submission) designed to establish bid prices at artificial, non-competitive levels for any wrongful gains, and to deprive the Procuring Agency of the benefits of free and open competition;

(b) The Procuring Agency will reject a proposal for award if it determines that the Bidder recommended for award has engaged in corrupt or fraudulent practices in competing for the contract in question;

(c) The Procuring Agency will sanction a firm, in accordance with prevailing Blacklisting procedures under Punjab Procurement Rules 2014, if it at any time determines that the firm has engaged in corrupt or fraudulent practices in competing for, or in executing, a Bank-financed contract.

34.2 Furthermore, Bidders shall be aware of the provision stated in sub-clause 5.4 and sub-clause 24.1 of the General Conditions of Contract.

Part-I

Section II. Bid Data Sheet

The following specific data for the goods to be procured shall complement, supplement, or amend the provisions in the Instructions to Bidders (ITB) Part One. Whenever there is a conflict, the provisions herein shall prevail over those in ITB.

Introduction	
ITB 1.1	Name of Procuring Agency: Project Management Unit (PMU) Primary & Secondary Health Department, Government of the Punjab
ITB 1.1	Name of Project: Revamping of DHQ /THQ Hospitals in Punjab
ITB 1.1	Name of Contract: Supply of Goods
ITB 4.1	Name of Purchaser: Project Management Unit (PMU), Revamping of DHQ /THQ Hospitals in Punjab
ITB 6.1	For clarification purposes, the Employer's address is: PMU, Revamping of DHQ /THQ Hospitals in Punjab, 31 /E1,Shahra-e-Imam Hussain, Gulberg III, Lahore Requests for clarification shall be received by the Employer no Later than 8th September, 2020
ITB 8.1	Language of the bid – English

Bid Price and Currency	
ITB 11.2	The price quoted shall be Delivered Duty Paid at the following locations in accordance with the Schedule of Requirements including the delivery charges: Lahore City (Punjab)
ITB 11.5	The price shall be in Pak Rupees and shall be fixed.

Preparation and Submission of Bids	
ITB 13.2	c. Certificate of Incorporation of bidder's firm showing its location and the date of registration etc. d. NTN and GST Registration Certificate
ITB 13.3 (b)	Audited Balance Sheet or Bank Statement for the last 2 financial years (up to June 2020).
ITB 13.3 (d)	**Qualification requirements**. In addition to ITB 13.1, ITB 13.2, and ITB 13.3 (b), the potential bidder must also fulfill the following:- h) The Bidder must be a **Manufacturer** or an **Authorized Dealer/Distributor** for sales & service continuously from last one-year. i) **Technical Brochures** of Equipment quoted, mentioning its specifications, manufacture's model, product number, and country of origin. j) An **average annual sale** of **Rs. 2 million** (for Package-1) k) The bidder must have at least one local certified /authorized **repair and maintenance set-up**. l) Description of bidder's own **repair & maintenance set-up** with the location / addresses of workshops, mobile workshops (if any). m) **Authority Letter** from the Bidder Company authorizing the relevant person to represent the company. n) If an Agent submits bids on behalf of more than one Manufacturer, unless each such bid is accompanied by a separate Bid Form for each bid, and a bid security, when required, for each bid, and a valid authorized dealership certificate from the respective Manufacturer, all such bids will be rejected as nonresponsive.
ITB 14.3 (b)	A certificate from the dealer that all spare parts of the equipment to be supplied are easily available in Pakistan in the local market or from company owned outlets.

<table>
<tr><td></td><td></td></tr>
<tr><td>ITB 15.1</td><td>Amount of Bid Security:

<table>
<tr><th>Package</th><th>Item</th><th>Bid Security</th></tr>
<tr><td>LOT-I</td><td></td><td></td></tr>
</table>

Bids shall be in the prescribed format, sealed and accompanied by the Bid Security in the form of Call Deposit, Bank Draft, or Pay Order in favor of Project Director-PMU, Primary & Secondary Healthcare Department having its validity 90 days from the date of opening of bid.</td></tr>
<tr><td>ITB 16.1</td><td>Bid Validity Period: 90 days after the date of opening of bid.</td></tr>
<tr><td>ITB 17.1</td><td>Number of Copies: Original along with one Copy of the bid. Bids must be accompanied by unit price and total price.</td></tr>
<tr><td>ITB 18.2 (a)</td><td>Address for Bid Submission:

Procurement Specialist, Project Management Unit (PMU), Revamping of DHQ /THQ Hospitals in Punjab, 31 /E1,Shahra-e-Imam Hussain, Gulberg III, Lahore</td></tr>
<tr><td>ITB 18.2 (b)</td><td>IFB Title and Number:

<u>Package-1</u></td></tr>
<tr><td>ITB 19.1</td><td>Deadline for Bid Submission: 22th September 2020 at 11:00 a.m</td></tr>
<tr><td>ITB 22.1</td><td>Time, Date, and Place for Bid Opening:

On 22th September 2020 at 11:30 a.m. at Office of Procurement Specialist, Project Management Unit (PMU), Revamping of DHQ /THQ Hospitals in Punjab, 31 /E1,Shahra-e-Imam Hussain, Gulberg III, Lahore</td></tr>
</table>

Bid Evaluation	
ITB 25.3	Criteria for bid evaluation: Lowest Delivered Duty Paid (DDP) Total Price offered by the qualified responsive bidder.

Contract Award	
ITB 29.1	Percentage for quantity increase or decrease: 15 % of total contract value

Section III. Schedule of Requirements

The delivery schedule expressed as weeks stipulates hereafter a delivery date which is the date of delivery required.

TABLE 1 DELIVERY SCHEDULE

Package-1	**Location**	**Item**	**Qty**	**Delivery Period** from the date of Advance Acceptance of Tender
LOT-I	*PMU, Lahore*			**8-10 Weeks**

Part-I

Section IV. Technical Specifications

CRITERIA FOR TECHNICAL EVALUATION OF THE TENDER (For Sample specific items)

The quotation /bid who secure 65% marks will qualify for the competition.

Sr. No.	Parameter	Weight age
1	Business Volume	
2	Age of Company/Firm	
3	Financial strength of the vender	
4	H.R. Strength	
5	Relevant experience	
6	Sample	
TOTAL		**100%**

Package-1 LOT-I: GOODS

BROAD SPECIFICATIONS:

Part-I

Section V. Bidding Forms

Bid Submission Form

Date: _____

No: _____

To

The Project Director,

Project Management Unit,

Primary & Secondary Health Department

Government of the Punjab

31/E1, Shahra-e-Imam Hussain, Gulberg III, Lahore.

Having examined the bidding documents including Addenda Nos. *[insert numbers],* the receipt of which is hereby duly acknowledged, we, the undersigned, offer to supply and deliver *[description of goods and services]* in conformity with the said bidding documents for the sum of *[total bid amount in words and figures]* or such other sums as may be ascertained in accordance with the Schedule of Prices attached herewith and made part of this Bid.

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

If our Bid is accepted, we will obtain the **guarantee of a bank in a sum equivalent to 5% percent of the Contract Price** for the due performance of the Contract, in the form prescribed by the Purchaser.

We agree to abide by this Bid for a period of 90 days from the date fixed for Bid opening under Clause 22 of the Instructions to Bidders, and it shall remain binding upon us and may be accepted at any time before the expiration of that period.

Until a formal Contract is prepared and executed, this Bid, together with your written acceptance thereof and your Advance Acceptance of Tender, shall constitute a binding Contract between us.

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

Name and address of agent	Amount and Currency	Purpose of Commission or gratuity
_____	_____	_____
_____	_____	_____
_____	_____	_____

(if none, state "none")

We understand that you are not bound to accept the lowest or any bid you may receive.

Dated this _____ day of _____ 20_____.

_____ _____

[signature] *[in the capacity of]*

Duly authorized to sign Bid for and on behalf of _____

Manufacturer's Authorization Form

[See Clause 13.3 (a) of the Instructions to Bidders.]

To: *[name of the Purchaser]*

WHEREAS *[name of the Manufacturer]* who are established and reputable manufacturers of *[name and/or description of the goods]* having factories at *[address of factory]*

do hereby authorize *[name and address of Agent]* to submit a bid, and subsequently negotiate and sign the Contract with you against IFB No. *[Reference of the Invitation to Bid]* for the above goods manufactured by us.

We hereby extend our full guarantee and warranty as per Clause 15 of the General Conditions of Contract for the goods offered for supply by the above firm against this Invitation for Bids.

_____

[signature for and on behalf of Manufacturer]

Note: This letter of authority should be on the letterhead of the Manufacturer and should be signed by a person competent and having the power of attorney to bind the Manufacturer. It should be included by the Bidder in its bid.

3. Price Schedules

Package 1: Blinds for Windows

Sr.	Item	Brand/Model/Origin	Qty	Unit Price (Rs.)	Total Amount (Rs.)
2					
				TOTAL AMOUNT (Rs.)	

Note:

2. In case of discrepancy between unit price and total, the unit price shall prevail.
3. The supplier has to provide the following free of cost:
   - vi. Technical and Operation Manual.
   - vii. At site complete training of Purchaser's nominated staff regarding maintenance and operation of Goods.
   - viii. Provide color picture/samples of all quoted items with detail specifications on company letter head and also provide brochures published by company/manufacturer(if available)
   - ix. On site One year parts and labor warranty for all components.
   - x. On site installation.

Part-II

Section I. Contract Forms

Contract Form

THIS AGREEMENT made the _____ day of _____ 20_____ between *[name of Purchaser]* (hereinafter called "the Purchaser") of the one part and *[name of Supplier]* of (hereinafter called "the Supplier") of the other part:

WHEREAS the Purchaser invited bids for certain goods and ancillary services, viz., *[brief description of goods and services]* and has accepted a bid by the Supplier for the supply of those goods and services in the sum of *[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 be deemed to form and be read and construed as part of this Agreement, viz.:

(a) the Bid Form and the Price Schedule submitted by the Bidder;
(b) the Schedule of Requirements;
(c) the Technical Specifications;
(d) the General Conditions of Contract;
(e) the Special Conditions of Contract; and
(f) the Purchaser's Advance Acceptance of Tender.

3. In consideration of the payments to be made by the Purchaser to the Supplier as hereinafter mentioned, the Supplier hereby covenants with the Purchaser to provide the goods and services and to remedy defects therein in conformity in all respects with the provisions of the Contract

4. The Purchaser hereby covenants to pay the Supplier in consideration of the provision of the goods and services and the remedying of defects therein, the Contract Price or such other sum as may become payable under the provisions of the contract at the times and in the manner prescribed by the contract.

IN WITNESS whereof the parties hereto have caused this Agreement to be executed in accordance with their respective laws the day and year first above written.

Signed, sealed, delivered by _____ the _____ (for the Purchaser)

Signed, sealed, delivered by _____ the _____ (for the Supplier

Performance Security Form

To:

The Project Director
Project Management Unit (PMU)
Revamping of DHQ /THQ Hospitals in Punjab
31/E1, Shahra-e-Imam Hussain, Gulberg III, Lahore.

WHEREAS *[name of Supplier]* (hereinafter called "the Supplier") has undertaken, in pursuance of Contract No. *[reference number of the contract]* dated _____ 20_____ to supply *[description of goods and services] (*hereinafter called "the Contract").

AND WHEREAS it has been stipulated by you in the said Contract that the Supplier shall furnish you with a bank guarantee by a reputable bank for the sum specified therein as security for compliance with the Supplier's performance obligations in accordance with the Contract.

AND WHEREAS we have agreed to give the Supplier a guarantee:

THEREFORE WE hereby affirm that we are Guarantors and responsible to you, on behalf of the Supplier, up to a total of *[amount of the guarantee in words and figures],* and we undertake to pay you, upon your first written demand declaring the Supplier to be in default under the Contract and without cavil or argument, any sum or sums within the limits of *[amount of guarantee]* as aforesaid, without your needing to prove or to show grounds or reasons for your demand or the sum specified therein.

This guarantee is valid until the _____ day of _____20_____.

Signature and seal of the Guarantors

_____

[name of bank or financial institution]

_____

[address]

_____

[date]

BID SECURITY (Bank Guarantee)

Security Executed on _____ (Date)

Name of Surety (Bank) with Address: _____

(Scheduled Bank in Pakistan)

Name of Principal (Bidder) with Address _____

_____

Penal Sum of Security Rupees. _____(Rs. _____) Bid Reference No. _____ KNOW ALL MEN BY THESE PRESENTS, that in pursuance of the terms of the Bid and at the request of the said Principal (Bidder) we, the Surety above named, are held and firmly bound unto _____ (hereinafter called the 'Employer') in the sum stated above for the payment of which sum well and truly to be made, we bind ourselves, our heirs, executors, administrators and successors, jointly and severally, firmly by these presents.

THE CONDITION OF THIS OBLIGATION IS SUCH, that whereas the Bidder has submitted the accompanying Bid dated _____ for Bid No. _____ for_____(Particulars of Bid) to the said Employer; and

WHEREAS, the Employer has required as a condition for considering said Bid that the Bidder furnishes a Bid Security in the above said sum from a Scheduled Bank in Pakistan or from a foreign bank duly counter-guaranteed by a Scheduled Bank in Pakistan, to the Employer, conditioned as under:

4. that the Bid Security shall remain in force up to and including the date---------- days after the deadline for validity of bids as stated in the Instructions to Bidders or as it may be extended by the Employer, notice of which extension(s) to the Surety is hereby waived;
5. that the Bid Security of unsuccessful Bidders will be returned by the Employer after expiry of its validity or upon signing of the Contract Agreement; and
6. That in the event of failure of the successful Bidder to execute the proposed Contract Agreement for such work and furnish the required Performance Security.

NOW THEREFORE, if the successful Bidder shall, within the period specified therefor, on the prescribed form presented to him for signature enter into a formal Contract with the said Employer in accordance with his Bid as accepted and furnish within--------- days of his being requested to do so, a Performance Security with good and sufficient surety, as may be required, upon the form prescribed by the said Employer for the faithful performance and proper fulfillment of the said Contract or in the event of non-withdrawal of the said Bid within the time specified for its validity then this obligation shall be void and of no effect, but otherwise to remain in full force and effect.

PROVIDED THAT the Surety shall forthwith pay the Employer (Procuring Agency) the said sum upon first written demand of the Employer (without cavil or argument) and without requiring the Employer to prove or to show grounds or reasons for such demand, notice of which shall be sent by the Employer by registered post duly addressed to the Surety at its address given above.

PROVIDED ALSO THAT the Employer shall be the sole and final judge for deciding whether the Principal (Bidder) has duly performed his obligations to sign the Contract Agreement and to furnish the requisite Performance Security within the time stated above, or has defaulted in fulfilling said requirements and the Surety shall pay without objection the said sum upon demand from the Employer forthwith and without any reference to the Principal (Bidder) or any other person.

IN WITNESS WHEREOF, the above bounden Surety has executed the instrument under its seal on the date indicated above, the name and seal of the Surety being hereto affixed and these presents duly signed by its undersigned representative pursuant to authority of its governing body.

SURETY (Bank)

WITNESS: Signature_____

3. _____ Name_____

   _____ Title_____

   Corporate Secretary (Seal) Corporate Guarantor (Seal)

4. _____

   _____

   Name, Title & Address

Part III

Section II. General Conditions of Contract

1 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) "The Goods" means all of the equipment, machinery, and/or other materials which the Supplier is required to supply to the Purchaser under the Contract.

(d) "The Services" means those services ancillary to the supply of the Goods, such as transportation and insurance, and any other incidental services, such as installation, commissioning, provision of technical assistance, training, and other such obligations of the Supplier covered under the Contract.

(e) "GCC" means the General Conditions of Contract contained in this section.

(f) "SCC" means the Special Conditions of Contract.

(g) "The Purchaser" means the organization purchasing the Goods, as named in SCC.

(h) "The Purchaser's country" is Islamic Republic of Pakistan.

(i) "The Supplier" means the individual or firm supplying the Goods and Services under this Contract.

(j) "The Project Site," where applicable, means the place or places named in SCC.

(k) "Day" means calendar day.

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

3. Country of Origin 3.2 For purposes of this Clause, "origin" means the place where the Goods were mined, grown, or produced, or from which the Services are supplied. Goods are produced when, through manufacturing, processing, or substantial and major assembly of components, a commercially recognized new product results that is substantially different in basic characteristics or in purpose or utility from its components.

3.3 The origin of Goods and Services is distinct from the nationality of the Supplier.

4. Standards 4.1 The Goods supplied under this Contract shall conform to the standards mentioned in the Technical Specifications, and, when no applicable standard is mentioned, to the authoritative standards appropriate to the Goods' country of origin. Such standards shall be the latest issued by the concerned institution.

5. Use of Contract Documents and Information; Inspection and Audit by the Bank

5.1 The Supplier shall not, without the Purchaser's prior written consent, disclose the Contract, or any provision thereof, or any specification, plan, drawing, pattern, sample, or information furnished by or on behalf of the Purchaser in connection therewith, to any person other than a person employed by the Supplier in the performance of the Contract. Disclosure to any such employed person shall be made in confidence and shall extend only so far as may be necessary for purposes of such performance.

5.2 The Supplier shall not, without the Purchaser's prior written consent, make use of any document or information enumerated in GCC Clause 5.1 except for purposes of performing the Contract.

5.3 Any document, other than the Contract itself, enumerated in GCC Clause 5.1 shall remain the property of the Purchaser and shall be returned (all copies) to the Purchaser on completion of the Supplier's performance under the Contract if so required by the Purchaser.

5.4 The Supplier shall permit the Procuring Agency to inspect the Supplier's accounts and records relating to the performance of the Supplier and to have them audited by auditors appointed by the Procuring Agency, if so required by the Procuring Agency.

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 Goods or any part thereof.

7. Performance Security

7.1 Within ten (10) 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 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 acceptable to the Purchaser and shall be in one of the following forms:

(a) a bank guarantee or an irrevocable letter of credit issued by a reputable bank located in Pakistan, in the form provided in the bidding documents or another form 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 SCC.

8. Inspections and Tests

8.1 The Purchaser or its representative shall have the right to inspect and/or to test the Goods to confirm their conformity to the Contract specifications at no extra cost to the Purchaser. 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.

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

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

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

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

9. Packing

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

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

10. Delivery and Documents

10.1 Delivery of the Goods shall be made by the Supplier in accordance with the terms specified in the Schedule of Requirements. The details of shipping and/or other documents to be furnished by the Supplier are specified in SCC.

10.2 Documents to be submitted by the Supplier are specified in SCC.

11. Insurance

11.1 The Goods supplied under the Contract shall be delivered duty paid (DDP) under which risk is transferred to the buyer after having been delivered; hence insurance coverage is seller's responsibility.

12. Transportation

12.1 The Supplier is required under the Contact to transport the Goods to a specified place of destination within the Purchaser's country, 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.

13. Incidental Services

13.1 The Supplier may be required to provide any or all of the following services, including additional services, if any, specified in SCC:

(a) performance or supervision of on-site assembly and/or start-up of the supplied Goods;

(b) furnishing of tools required for assembly and/or maintenance of the supplied Goods;

(c) furnishing of a detailed operations and maintenance manual for each appropriate unit of the supplied Goods;

(d) performance or supervision or maintenance and/or repair of the supplied Goods, for a period of time agreed by the parties, provided that this service shall not relieve the Supplier of any warranty obligations under this Contract; and

(e) Training of the Purchaser's personnel, at the Supplier's plant and/or on-site, in assembly, start-up, operation, maintenance, and/or repair of the supplied Goods.

13.2 Prices charged by the Supplier for incidental services, if not included in the Contract Price for the Goods, shall be agreed upon in advance by the parties and shall not exceed the prevailing rates charged for other parties by the Supplier for similar services.

14. Spare Parts

14.1 As specified in SCC, the Supplier may be required to provide any or all of the following materials, notifications, and information pertaining to spare parts manufactured or distributed by the Supplier:

(a) such spare parts as the Purchaser may elect to purchase from the Supplier, provided that this election shall not relieve the Supplier of any warranty obligations under the Contract; and

(b) in the event of termination of production of the spare parts:

(i) advance notification to the Purchaser of the pending termination, in sufficient time to permit the Purchaser to procure needed requirements; and

(ii) Following such termination, furnishing at no cost to the Purchaser, the blueprints, drawings, and specifications of the spare parts, if requested.

15. Warranty

15.1 The Supplier warrants that the Goods supplied under the Contract are new, unused, of the most recent or current models and those they incorporate all recent improvements in design and materials unless provided otherwise in the Contract. The Supplier further warrants that all Goods supplied under this Contract shall have no defect, arising from design, materials, or workmanship (except when the design and/or material is required by the Purchaser's specifications) or from any act or omission of the Supplier, that may develop under normal use of the supplied Goods in the conditions prevailing in the country of final destination.

15.2 This warranty shall remain valid for twelve (12) months after the Goods, or any portion thereof as the case may be, have been delivered to and accepted at the final destination indicated in the Contract, or for eighteen (18) months after the date of shipment from the port or place of loading in the source country, whichever period concludes earlier, unless specified otherwise in SCC.

15.3 The Purchaser shall promptly notify the Supplier in writing of any claims arising under this warranty.

15.4 Upon receipt of such notice, the Supplier shall, within the period specified in SCC and with all reasonable speed, repair or replace the defective Goods or parts thereof, without costs to the Purchaser.

15.5 If the Supplier, having been notified, fails to remedy the defect(s) within the period specified in SCC, within a reasonable period, the Purchaser may proceed to take such remedial action as may be necessary, at the Supplier's risk and expense and without prejudice to any other rights which the Purchaser may have against the Supplier under the Contract.

16. Payment

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

16.2 The Supplier's request(s) for payment shall be made to the Purchaser in writing, accompanied by an invoice describing, as appropriate, the Goods delivered and Services performed, and by documents submitted pursuant to GCC Clause 10, and upon fulfillment of other obligations stipulated in the Contract.

16.3 Payments shall be made promptly by the Purchaser, but in no case later than thirty (30) days after submission of an invoice or claim by the Supplier.

16.4 The currency of payment is Pak. Rupees

17. Prices

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

18. Change Orders

18.1 The Purchaser may at any time, by a written order given to the Supplier pursuant to GCC Clause 31, make changes within the general scope of the Contract in any one or more of the following:

(a) drawings, designs, or specifications, where Goods to be furnished under the Contract are to be specifically manufactured for the Purchaser;

(b) the method of shipment or packing;

(c) the place of delivery; and/or

(d) the Services to be provided by the Supplier.

18.2 If any such change causes an increase or decrease in the cost of, or the time required for, the Supplier's performance of any provisions under the Contract, an equitable adjustment shall be made in the Contract Price or delivery schedule, or both, and the Contract shall accordingly be

amended. Any claims by the Supplier for adjustment under this clause must be asserted within thirty (30) days from the date of the Supplier's receipt of the Purchaser's change order.

19. Contract Amendments

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

20. Assignment

20.1 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.

21. Subcontracts

21.1 The Supplier shall notify the Purchaser in writing of all subcontracts awarded under this Contract if not already specified in the bid. Such notification, in the original bid or later, shall not relieve the Supplier from any liability or obligation under the Contract.

21.2 Subcontracts must comply with the provisions of GCC Clause 3.

22. Delays in the Supplier's Performance

22.1 Delivery of the Goods and performance of Services shall be made by the Supplier in accordance with the time schedule prescribed by the Purchaser in the Schedule of Requirements.

22.2 If at any time during performance of the Contract, the Supplier or its subcontractor(s) should encounter conditions impeding timely delivery of the Goods and performance of Services, the Supplier shall promptly notify the Purchaser in writing of the fact of the delay, its likely duration and its cause(s). As soon as practicable after receipt of the Supplier's notice, the Purchaser shall evaluate the situation and may at its discretion extend the Supplier's time for performance, with or without liquidated damages, in which case the extension shall be ratified by the parties by amendment of Contract.

22.3 Except as provided under GCC Clause 25, a delay by the Supplier in the performance of its delivery obligations shall render the Supplier liable to the imposition of liquidated damages pursuant to GCC Clause 23, unless an extension of time is agreed upon pursuant to GCC Clause 22.2 without the application of liquidated damages.

23. Liquidated Damages

23.1 Subject to GCC Clause 25, if the Supplier fails to deliver any or all of the Goods or to perform the Services within the period(s) specified in the Contract, the Purchaser shall, without prejudice to its other remedies under the Contract, deduct from the Contract Price, as liquidated damages, a sum equivalent to the percentage specified in SCC of the delivered price of the delayed Goods or unperformed Services for each week or part thereof of delay until actual delivery or performance, up to a maximum deduction of the percentage specified in SCC. Once the maximum is reached, the Purchaser may consider termination of the Contract pursuant to GCC Clause 24.

24. Termination for Default

24.1 The Purchaser, without prejudice to any other remedy for breach of Contract, by written notice of default sent to the Supplier, may terminate this Contract in whole or in part:

(a) if the Supplier fails to deliver any or all of the Goods within the period(s) specified in the Contract, or within any extension thereof granted by the Purchaser pursuant to GCC Clause 22; or

(b) if the Supplier fails to perform any other obligation(s) under the Contract.

(c) if the Supplier, in the judgment of the Purchaser has engaged in corrupt or fraudulent practices in competing for or in executing the Contract.

For the purpose of this clause:

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

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

24.2 In the event the Purchaser terminates the Contract in whole or in part, pursuant to GCC Clause 24.1, the Purchaser may procure, upon such terms and in such manner as it deems appropriate, Goods or Services similar to those undelivered, and the Supplier shall be liable to the Purchaser for any excess costs for such similar Goods or Services. However, the Supplier shall continue performance of the Contract to the extent not terminated.

25. Force Majeure

25.1 Notwithstanding the provisions of GCC Clauses 22, 23, and 24, the Supplier shall not be liable for forfeiture of its performance security, liquidated damages, or termination for default if and to the extent that it's delay in performance or other failure to perform its obligations under the Contract is the result of an event of Force Majeure

25.2 For purposes of this clause, "Force Majeure" means an event beyond the control of the Supplier and not involving the Supplier's fault or negligence and not foreseeable. Such events may include, but are not restricted to, acts of the Purchaser in its sovereign capacity, wars or revolutions, fires, floods, epidemics, quarantine restrictions, and freight embargoes.

25.3 If a Force Majeure situation arises, the Supplier shall promptly notify the Purchaser in writing of such condition and the cause thereof. Unless otherwise directed by the Purchaser in writing, the Supplier shall continue to perform its obligations under the Contract as far as is reasonably practical, and shall seek all reasonable alternative means for performance not prevented by the Force Majeure event

26. Termination for Insolvency

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

right of action or remedy which has accrued or will accrue thereafter to the Purchaser.

27. Termination for Convenience

27.1 The Purchaser, by written notice sent to the Supplier, may terminate the Contract, in whole or in part, at any time for its convenience. The notice of termination shall specify that termination is for the Purchaser's convenience, the extent to which performance of the Supplier under the Contract is terminated, and the date upon which such termination becomes effective.

27.2 The Goods that are complete and ready for shipment within thirty (30) days after the Supplier's receipt of notice of termination shall be accepted by the Purchaser at the Contract terms and prices. For the remaining Goods, the Purchaser may elect:

(a) to have any portion completed and delivered at the Contract terms and prices; and/or

(b) to cancel the remainder and pay to the Supplier an agreed amount for partially completed Goods and Services and for materials and parts previously procured by the Supplier.

28. Resolution of Disputes

28.1 The Purchaser and the Supplier shall make every effort to resolve amicably by direct informal negotiation any disagreement or dispute arising between them under or in connection with the Contract.

28.2 If, after thirty (30) days from the commencement of such informal negotiations, the Purchaser and the Supplier have been unable to resolve amicably a Contract dispute, either party may require that the dispute be referred for resolution to the formal mechanisms specified in SCC. These mechanisms may include, but are not restricted to, conciliation mediated by a third party, adjudication in an agreed and/or arbitration.

29. Governing Language

29.1 The Contract shall be written in the language specified in SCC. Subject to GCC Clause 30, the version of the Contract written in the specified language shall govern its interpretation. All correspondence and other documents pertaining to the Contract which are exchanged by the parties shall be written in the same language.

30. Applicable Law

30.1 The Contract hall be interpreted in accordance with the laws of Islamic Republic of Pakistan.

31. Notices

31.1 Any notice given by one party to the other pursuant to this Contract shall be sent to the other party in writing or by fax and confirmed in writing to the other party's address specified in SCC.

31.2 A notice shall be effective when delivered or on the notice's effective date, whichever is later.

32. Taxes and Duties

32.1 Supplier shall be entirely responsible for all taxes, duties, license fees, etc., incurred until delivery of the contracted Goods to the Purchaser.

Part-II

Section III. Special Conditions of Contract

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

1. Definitions (GCC Clause 1)

GCC 1.1 (g)—The Purchaser is: Procurement Specialist, Project Management Unit (PMU), Revamping of DHQ/THQ Hospitals in Punjab, Primary & Secondary Health Department, Government of the Punjab 31-E/1, Shahra-e-Imam Hussain, Gulberg-III, Lahore.

GCC 1.1 (h)—The Purchaser's country is: Islamic Republic of Pakistan

GCC 1.1 (i)—The Supplier is:

GCC 1.1 (j)—The Project Site is: Lahore City (Punjab).

2. Country of Origin (GCC Clause 3)

3. Performance Security (GCC Clause 7)

GCC 7.1—The amount of performance security, as a percentage of the Contract Price, shall be *5%* (Five per cent of the contract price) in the shape of non recourse, irrevocable and unconditional bank guarantee from scheduled bank of Pakistan on the prescribed format attached with the bidding document.

4. Inspections and Tests (GCC Clause 8)

GCC 8.6—

Inspection and tests prior to delivery of goods and at final acceptance are:-

vi) For being Brand New, bearing relevant reference numbers of the equipment (Certificate from supplier)
vii) For Physical Fitness having No Damages (Certificate from supplier)
viii) For the Country of Origin as quoted by the Supplier (Certificate from manufacturer)
ix) For conformance to specifications and performance parameters, through Prior to delivery inspection (Inspection Report by PMU)
x) For successful operation at site after complete installation, testing and commissioning of the equipment (Installation, Testing and Commissioning Report by PMU)

5. Delivery and Documents (GCC Clause 10)

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

(i) Copies of the Supplier's invoice showing Goods' description, quantity, unit price, and total amount;

(ii) Original and two copies of the usual transport document (for example, a negotiable bill of lading, a non-negotiable sea waybill, an inland waterway document, an air waybill, a railway consignment note, a road consignment note, or a multimodal transport document) which the buyer may require to take the goods;

(iii) Copies of the packing list identifying contents of each package;

(iv) Insurance Certificate;

(v) Manufacturer's or Supplier's Valid Warranty Certificate;

(vi) Inspection Certificate issued by the Nominated Inspection Agency (if any), and the Supplier's Factory Inspection Report; and

(vii) Certificate of Origin.

(viii) The above documents would be required even if the equipment has already been imported and is available with the supplier ex-stock

6. Insurance (GCC Clause 11)

GCC 11.1— The Goods supplied under the Contract shall be Delivered Duty Paid (DDP) under which risk is transferred to the Buyer after having been delivered. Hence insurance coverage is seller's responsibility. Since the Insurance is seller's responsibility they may arrange appropriate coverage.

7. Incidental Services (GCC Clause 13)

GCC 13.1—Incidental services to be provided are:

C) At site complete training of Purchaser's nominated staff regarding maintenance and operation of Goods.

D) At site preventive maintenance on quarterly basis by the bidder's qualified staff for one year, starting from final acceptance of goods.
The rate must include cost for all kinds of labor, inputs and material required for above, and all applicable government taxes and levies. In case a separate rate is not provided by the bidder for the above items, it shall be deemed to have been covered in the overall quoted cost.

8. Warranty (GCC Clause 15)

GCC 15.2—In accordance with the provisions, the warranty period shall be 2000 hours of operation or 12 months (parts and labor warranty) from date of Handing Over (Final Acceptance) of the Goods whichever occurs earlier. The Supplier shall, in addition, comply with the performance and/or consumption guarantees specified under the Contract. If, for reasons attributable to the Supplier, these guarantees are not attained in whole or in part, the Supplier shall, at its discretion, either:

(a) Make such changes, modifications, and/or additions to the Goods or any part thereof as may be necessary in order to attain the contractual guarantees specified in the Contract at its own cost and expense and to carry out further performance tests in accordance with SCC 4,

or

(b) Pay liquidated damages to the Purchaser with respect to the failure to meet the contractual guarantees. The rate of these liquidated damages shall be 0.1 % of the contract price per day. The maximum amount of liquidated damages for the whole of the goods or part thereof shall be 5% of the contract price.

or

(c) Replacement of the whole unit at site including transportation, installation, testing & commissioning etc in case of major defect at his own cost.

GCC 15.4 & 15.5—the period for correction of defects in the warranty period is 72 hours.

9. Payment (GCC Clause 16)

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

Payment for Goods supplied:

Payment shall be made in Pak. Rupees in the following manner:

(ii) **Payment against Delivered Goods**: Upon submission of claim, the supplier shall be paid within thirty (30) days of receipt of the Goods at site after performing the requisite inspection and tests as mentioned in SCC 4.

12. Prices (GCC Clause 17)

GCC 17.1—Prices shall be: Fixed.

13. Liquidated Damages (GCC Clause 23)

GCC 23.1—Applicable rate: 0.1 % of contract price per day

Maximum deduction: 5 % of contract price

14. Resolution of Disputes (GCC Clause 28)

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

In the case of a dispute between the Purchaser and the Supplier, the dispute shall be referred to adjudication or arbitration in accordance with the Pakistan Arbitration Act, 1940.

15. Governing Language (GCC Clause 29)

GCC 29.1—The Governing Language shall be: English.

16. Applicable Law (GCC Clause 30)

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

The Employment of Children (ECA) Act 1991

The Bonded Labour System (Abolition) Act of 1992

The Factories Act 1934

17. Notices (GCC Clause 31)

GCC 31.1—Purchaser's address for notice purposes – Office of Project Director, Project Management Unit (PMU), Revamping of DHQ /THQ Hospitals in Punjab, Primary & Secondary Health Department, Government of Punjab, 31/E1, Shahra-e-Imam Hussain, Gulberg III, Lahore.

—Supplier's address for notice purposes:

10 References

1 www.ppra.punjab.gov.pk
2 www.worldbank.org
3 www.dra.gov.pk
4 www.finance.punjab.gov.pk/rules