6 Developing Bidding Documents and Inviting Offers

Three Phases	*Ten Elements*
I. Program Planning	**1. Defining Reproductive Health Supply Requirements**
	2. Specifications
	3. Assessment of Procurement Options
	4. Budget, Funding, and Procurement Requisition
II. Procurement Process	**5. Procurement Planning**
	6. Developing Bidding Documents and Inviting Offers
	7. Selecting Suppliers
	8. Contracts
III. Performance	**9. Contract Performance and Monitoring**
	10. Delivery of Goods

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A. Introduction

In public-sector competitive procurement, the procuring entity prepares and sells (or provides) detailed bidding documents to potential suppliers. These documents explain all the requirements of what is to be supplied, all rules and procedures for bidding, and specific criteria that will be used to choose a winning bid. Some sections of the bidding documents also become part of the future contract between the supplier and the purchaser.

Module 6 describes the form and content of good public-sector bidding documents and explains how they are developed using information provided in the procurement requisition (Element 4) and the procurement plan (Element 5). Documents for contraceptive and pharmaceutical procurement are featured because these products have a special market environment and require different handling than most other goods.

The information in this module is important to reproductive health (RH) supply purchasers because:

- Good documents vastly reduce problems during the procurement process regarding bidding, evaluation, and contract award.
- Bidding documents provide a key opportunity to protect against counterfeit, fake, and possibly unsafe products.
- Bidding documents set up rules and expectations for contract performance—including timely delivery of the product.

The objective of this module is to help RH purchasers through the process of developing public-sector bidding documents and inviting offers that will result in timely delivery of high-quality products.

B. Learning Objectives

At the end of this module, the reader will be able to:

- Describe the important components of good public-sector bidding documents.
- Prepare good public-sector bidding documents.
- Invite and receive bids from suppliers.

C. Components, Considerations, and Challenges

1. Components

The two main components of Element 6 are developing documents and soliciting bids and offers.

a. Developing Documents

- For sealed, competitive bidding (see Sections D and E).
- For prequalification (see Section G).
- For Request for Quotation/negotiated procurement (see Section H).

b. Soliciting Bids and Offers

- Inviting and receiving bids (Section F).

2. Considerations

The main considerations for Element 6 are:

a. Overarching Principles of Quality and Timeliness

Bidding document clauses provide health-sector purchasers with a key opportunity to protect against counterfeit, fake, and possibly unsafe products.

Public-sector competitive procurement is a long process even when everything goes according to schedule. Complete, well-prepared bidding documents can significantly improve the chances of trouble-free bidding, award, and contract performance, which, in turn, affects the timeliness of the delivery.

Efficiency of the procuring entity itself is a factor in timeliness; it must produce bidding documents within the scheduled period or the entire process will be delayed, including product delivery.

b. Critical Component: None

There is no critical component in Element 6; that is, nothing that would entirely stop the supply of RH goods at this point in the process. However, the bidding documents do affect the signed contract, which is the next critical component.

c. Required Input From Other Elements

- Official procurement requisition.
- Procurement plan and schedule.
- Informal information from personnel who developed the procurement requisition and the procurement plan.

d. Applicable Rules for Procurement

Most procuring agencies in the public sector use standard bidding documents that include mandatory national public-sector procurement laws and any requirements stipulated by the funders.

e. Key Decision Points

- Eligibility criteria.
- Qualification requirements and evidence required.
- Evaluation criteria and evidence required.
- Quality assurance (QA) provisions for the contract.

f. Expected Output

- Bidding documents for sale or provision to prospective bidders, including a draft contract.
- Notifications, advertisements, and a direct Invitation for Bids.

3. Challenges

- Finding or developing model bidding documents that are appropriate for the RH purchaser's circumstances.
- Finding or reaching decisions on details that must be included in the bidding documents.
- Thinking through potential problems and addressing them in the bidding documents.
- Using clear wording and consistency across different sections of the document.
- Building in product quality protections.

- Making sure that the purchaser's responsibility (commitment) as outlined in the bidding documents actually happens, thus reducing the chance of bidder protest, which often leads to delayed delivery.
- Making sure bidding documents are correct and complete in every way, because under the rules of public procurement, nothing can be changed after bids are opened, even if a mistake is discovered.

D. Documents for Public-Sector Competitive Bidding

Good public-sector bidding documents include:

- Instructions, rules, and procedures for bidding.
- Information about where and when bids will be opened.
- Information about how bids will be evaluated and how the purchaser will select the winning bid.
- Information about any factors in addition to price that the purchaser will consider.
- Specifications such as product information, QA, and licensing requirements.
- Quantity, delivery dates, and place (requirements).
- Terms and conditions for the future contract between the purchaser and the winning bidder.
- Sample forms containing necessary wording for the bidder to use.

Most public-sector purchasers prepare bidding documents by following a model that has been developed by legal and procurement experts and adopted by the organization's governing authority. These "standard bidding documents" are multifaceted, carefully worded, and normally quite lengthy. They embody principles of good public-sector procurement and provide for the rights and protections of both the purchaser and the supplier with fixed wording or "boilerplate" sections of fixed clauses. The user "fills in the blanks" with wording appropriate to the requirements of the particular procurement action and may make minor adjustments to the boilerplate.

Model bidding documents of various organizations are often published on websites and can be obtained in print as well. Section I.3 of this module includes a list of websites where good public-sector procurement documents can be found. Serious students should obtain and study at least one set in conjunction with the material presented in this module. RH purchasers are asked to focus their attention on the World Bank's *Standard Bidding Document: Procurement of Health Sector Goods* (revised August 2008), which makes adjustments for the special nature of pharmaceuticals, vaccines, and condoms. Other types of contracts, such as framework agreements, are discussed in Module 8.

1. Layout of Model Bidding Documents

Most model bidding documents are organized into sections, each serving a different purpose. For example, the first section may cover everything a bidder would need to know about preparing and submitting a bid; where, when, and how bids will be opened; how bids will be evaluated; how and when the contract will be awarded; and warnings about the consequences of fraud and corruption. Qualification and eligibility requirements for the bidder might be located here or in a separate section. Another part of the document would cover terms and conditions of the future contract. Yet another would contain technical specifications, including QA and licensing requirements. Quantities, delivery dates, and delivery locations might be included in the specifications or noted separately. Sample forms for the bidder to use are often provided near the end of the document.

The main sections and their various clauses are sequenced differently from model to model, and precise wording may differ, but overall, their content is very similar.

The general sections of the model bidding documents contain mandatory standard clauses and are usually followed by special sections that contain modifying clauses to the standard sections. Modifying clauses provide a place for the purchaser to modify or add wording that addresses the specific goods and any unique procurement circumstances. The clauses in the Special Conditions of Contract are numbered to reference the corresponding clauses in the General Conditions of Contract. The same relationship is true for the clauses in the Special Instructions to Bidders (ITB) and the General Instructions to Bidders. For example, a clause numbered ITB 7.1 in Special Instructions to Bidders would directly tie back to Clause 7.1 in General Instructions to Bidders. Some bidding documents also use a coding system to indicate standard clauses that have modifying clauses in other sections. This is a very helpful tool, particularly for inexperienced staff. If the RH purchaser's bidding documents lack this feature, it should be added for future efficiency. Exhibit 6-1 on the following page shows this relationship and summarizes the basic function of each section of the bidding documents: General Instructions to Bidders, General Conditions of Contract, and sample forms contain mandatory standard clauses, while the Special Instructions to Bidders and Special Conditions of Contract sections contain modifying clauses.

Exhibit 6-1

Bidding Document Sections

Bidding Document Sections			
	Mandatory Standard Clauses	**Modifying Clauses**	**Function**
(a)	General Instructions to Bidders		General procedures for preparation and submission of bids, bid opening, evaluation, and award of contract
(b)		Special Instructions to Bidders	Modifies and expands general procedures and instructions (above) to suit specific goods and situations, including eligibility and qualification requirements
(a) and (b) above must be read together in order to correctly understand the procedures for bidding, what needs to be included in a bid, and how the winning bid will be chosen.			
(c)	General Conditions of Contract		Mandatory contract wording for issues such as payments, obligations, risks, rights, and performance; generally prepared by the funder's legal department
(d)		Special Conditions of Contract	Modifies or adds to general conditions (above) to suit specific goods and situations
(c) and (d) above must be read together in order to correctly understand what terms and conditions will apply to the contract.			
(e)		Technical Specifications	Detailed description of specific goods required, including applicable standards; packaging, packing, and markings; regulatory requirements; certifications; QA criteria; and acceptance criteria
(f)		Schedule of Requirements	Brief description of goods required, quantities, delivery schedule and location, and any special information or requirements pertaining to the deliveries
(g)	Sample Forms		Examples: Bid form (for signatures), price schedule, bid security, Contract Agreement, performance security, manufacturer's authorization, Certificate of Pharmaceutical Product

2. Description of Model Bidding Documents

The names of bidding document sections and their precise content may vary from model to model, but the following list represents the essence of good public-sector bidding documents:

a. General Instructions to Bidders.

b. Special Instructions to Bidders.

c. Eligible/Ineligible Countries or Suppliers.

d. General Conditions of Contract.

e. Special Conditions of Contract.

f. Technical Specifications.

g. Schedule of Requirements.

h. Evaluation Criteria.

i. Qualification Criteria.

j. Bid and Contract Forms.

Each of these key bidding document components is discussed below.

a. General Instructions to Bidders

Provides information to help bidders prepare and submit their bids; explains rules and procedures with regard to:

- Bid submission.
- Bid opening.
- Bid evaluation.
- Award of the contract.
- Definitions and warnings about fraud and corruption.

General Instructions to Bidders are mandatory standard clauses that must be included in the bidding documents without making any changes to the wording whatsoever. Information specific to the procurement action is supplied through corresponding modifying clauses located in different sections of the bidding documents.

b. Special Instructions to Bidders

Provides information specific to the procurement action; the procuring entity uses this section to supplement and/or modify General Instructions to Bidders. It has various titles; for example, in World Bank bidding documents, this section is called the "Bid Data Sheet." This module will use "Special Instructions to Bidders" in order to convey the relationship to the mandatory standard clauses. Special Instructions to Bidders includes, but is not limited to, variables such as:

- Amount and type of bid security, if required.
- Directions for submitting bids, including markings and time frame.
- Date, time, and other specific information about the bid opening.
- Specific criteria that will be used to evaluate bids, including any factors other than price that will be applied.
- Criteria for eligibility of goods and the particular documents required to establish goods' eligibility and conformity to bidding documents.
- Criteria for eligibility and qualification of bidders and the particular documents required to establish the bidder's eligibility and qualification.
- Specific information about awarding the contract.

c. Eligible/Ineligible Countries or Suppliers

Lists countries and firms that are excluded from bidding on specific contracts:

- Governments and other authorities may ban trade with certain countries and will generally list the banned countries on a website or specifically inform procuring entities.
- Firms that have defaulted on previous contracts or have violated anticorruption rules are often "debarred" by governments and have their names published on a public website.

d. General Conditions of Contract

Consists of mandatory standard clauses that will apply to the future contract; this section must be included in the bidding documents without making any changes to the wording whatsoever. General Conditions of Contract cover ordinary contract issues such as:

- Delivery.
- Payments.
- Warranty.
- Termination.
- Force majeure.
- Governing language.
- Notices.

e. Special Conditions of Contract

Provides modifying clauses for the contract specific to the procurement action; the procuring entity uses this section to supplement and/or modify like-numbered standard clauses in the General Conditions of Contract. The Special Conditions also addresses unique requirements of the procurement, such as:

- Regulatory compliance issues.
- Preshipment inspection and testing (critical to condom procurement).

f. Technical Specifications (prepared by purchaser's technical expert)

These specifications provide a precise technical description of the goods to be supplied. The procuring entity inserts the specifications, provided by the technical expert, into the bidding documents without modification.

Technical specifications are one of the most important parts of procurement. They constitute the benchmark against which the purchaser will judge the technical responsiveness of the bids. They must include a complete description of the product, presented in an industry-standard vocabulary and format, which includes, but is not limited to:

- Technical and performance characteristics.
- Size, units, quantity, and intended use.
- Packaging, packing, and markings.

- Regulatory requirements.
- Applicable standards and required certifications.
- QA criteria, including detailed tests required.
- Acceptance criteria.
- Detailed activities to be performed by the supplier.
- List of detailed functional guarantees covered by the warranty.

In addition to specifications that are clear, accurate, and complete, public-sector procurement requires that specifications be prepared in a way that will encourage maximum competition. They must be "product neutral." In other words, they must use generic terms, relative characteristics, and performance requirements rather than brand names and superficial descriptions.

The World Bank's *Standard Bidding Document: Procurement of Health Sector Goods* includes several pages of instruction about technical specifications and provides three sample specifications, one each for pharmaceuticals, vaccines, and condoms.

> Please review the additional guidance on technical specifications found in Module 2 of this *Toolkit*.

g. Schedule of Requirements

Lists goods and required delivery schedules; the procuring entity prepares a simple table showing:

- Number (bid, other relevant references).
- Named items required for purchase.
- Quantities and unit of measure.
- Delivery schedule.
- Mode of shipment.

Special notes may be included as necessary.

h. Evaluation Criteria

Criteria will be used to determine the lowest evaluated cost bid. Evaluation criteria are limited to price, price adjustments, and application of economic factors (nonfinancial items

given a value). The bidding documents should include the evaluation criteria to ensure an open and transparent bidding process. This information also provides bidders with insight on the criteria of importance for the purchaser.

i. Qualification Criteria

Lists the criteria that bidders must meet in order for their bids to be considered. Qualification criteria usually include, but are not limited to:

- Financial capability in terms of average annual turnover during each of the past 3 years, as evidenced by audited financial statements.
- Experience and technical capacity demonstrated by the number of years manufacturing and/or selling the goods to be supplied; completed contracts of a similar nature, with contact information for verification; and bank references.
- Licensing by the national regulatory authority (NRA) (in the case of pharmaceuticals, contraceptives, vaccines, etc.).
- Indicators of product quality.
- Local representation.

j. Bid and Contract Forms

Appropriate forms to be used by bidders in submitting their offers, and by the winning bidder in validating the contract award.

Bid submission form

Binds the successful bidder to conditions set out in the bidding documents and becomes a temporary contract when the award is notified.

Price schedule

Includes itemized charges for unit prices of goods, domestic value added (if this applies), freight, and insurance.

May separate foreign and domestic bidders in order to calculate a margin of preference for locally manufactured products (this is often for contracts financed under a World Bank loan or development credit).

Specification submission sheet (optional)

Includes verification of country of origin, make and model (when applicable), and full technical specifications and standards.

Completed forms are used by the evaluation committee to compare against requirements stated in the bidding documents.

Bidder information form
Eligibility and qualification information.

Legal status and authorized agent information.

Manufacturer's authorization letter
To be completed and signed by the manufacturer of the goods if the bidder is not the manufacturer.

Authorizes named party to submit a bid.

Confirms warranty obligation.

For a sample of the manufacturer's authorization letter, see Section I.2.d.

Bid security form
To be filled in and signed by the guarantor (bank or insurance company), or the bid security form can be used as an example for the supplier to create on its own letterhead.

Guarantor's undertaking to pay a specified amount if the bidder fails to go forward with an awarded contract.

Contract agreement form
To be signed by the purchaser and the winning bidder; incorporates relevant sections of bidding documents into the binding contract:

- Contract Agreement.
- General and Special Conditions of Contract.
- Technical Specifications.
- Schedule of Requirements.
- Supplier's bid and original price schedules.
- Purchaser's notification of award.
- Any other documents specified by the purchaser.

Performance security form

To be filled in and signed by the guarantor (bank or insurance company) or used as an example for a document on its own letterhead.

Guarantor's undertaking to pay a specified amount if the bidder defaults on an awarded contract.

Bank guarantee for advance payment

To be filled in and signed by the guarantor (bank or insurance company), or the bid security form can be used as an example for the supplier to create on its own letterhead.

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

Certificate of Pharmaceutical Product

To be provided by the manufacturer of the pharmaceutical product.

Establishes status with regard to certifications, licensing, and marketing according to the World Health Organization (WHO) Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce.[1] The Certification Scheme was developed by WHO to help combat the sale and distribution of substandard and/or counterfeit pharmaceutical products.

3. Clauses in Model Bidding Documents

Model bidding documents of different public-sector organizations are made up of very similar clauses because they are based on the same principles of good public-sector procurement. Differences, when they do occur, are generally attributable to:

- Slightly different ways of accomplishing the same objective.
- Incorporation of wording specific to local issues and experience.
- Incorporation of clauses specific to the type of goods to be purchased.
- Incorporation of issues important to the funding source.
- Incorporation of clauses specific to international trade as differentiated from local procurement.

[1] **Available at: http://www.who.int/medicines/areas/quality_safety/regulation_legislation/certification/en/index.html.**

In most cases, government documents focus on local bidding, while development bank documents and many donor-generated documents assume international bidding. This module will use international bidding as a tool for instruction.

Document "a" in Section I.2 is a list of mandatory standard clauses commonly found in bidding documents for goods procurement. It is in two parts: General Instructions to Bidders and General Conditions of Contract. A cursory review of this list will help readers understand the number and depth of issues that must be addressed in good bidding documents.[2] In particular, it should help new procuring entities understand the value of using model bidding documents rather than trying to develop them on their own. It can also be useful as a checklist to help ensure important clauses are included in the bidding documents.

[2] **For samples of actual wording used in these clauses, readers should look at the latest World Bank documents or at equivalent good public-sector procurement documents. Relevant websites and documents are listed in Section I.**

E. Preparing Draft Bidding Documents

The drafting process can be approached in two ways:

- Using model bidding document templates in electronic form, with purchasers filling in the particulars.
- Using model bidding documents, with purchasers rewriting them to suit their particular needs and situations.

The advantage of using an electronic copy is speed and accuracy. In either case, treatment of a particular topic must be consistent from section to section, and extreme care must be taken to avoid language that contradicts, overlaps, or duplicates wording in another section.

This poses a challenge for the procurement staff during the drafting process because changes in one part often require changes in another, and basic principles set out in the mandatory clauses must not be violated.

1. Study and Assessment

As soon as basic procurement requirements and the procurement method are known, the procurement staff can begin to become familiar with the applicable standard document and make a list of information that will need to be filled in. It is not necessary to wait until every question associated with the procurement plan and schedule is answered. This is particularly important for newer, less experienced procuring entities in order to help ensure that bidding documents will be produced within the scheduled period.

Assuming the RH purchaser has selected model bidding documents with appropriate fixed wording and will proceed by filling in the particulars, the process for developing the draft bidding documents begins with a careful study of the clauses and layout. The end result of this step should be a listing of information that must be assembled for the bidding documents. In addition to the list, this study will impart a good understanding of:

- How the procurement process is expected to proceed.
- Rules that must be followed.
- General intent (for example, fair competition).
- Recurring topic areas.
- Where various clauses are located and how they fit together.

- Potential problem areas.
- Responsibilities of the purchaser.
- Responsibilities of the bidder.
- Responsibilities of the eventual supplier.

Since each section of the bidding documents has a different purpose, the same topic often appears in several locations. For example, clauses on QA might appear in General Instructions to Bidders, Special Instructions to Bidders, General Conditions of Contract, Special Conditions of Contract, and Technical Specifications.

a. Read and Understand

It is very important for procurement personnel to read and understand mandatory standard clauses (in this module, General Instructions to Bidders and General Conditions of Contract) along with modifying clauses (Special Instructions to Bidders and Special Conditions of Contract) located in other parts of the bidding documents. Modifying clauses often do not repeat enough information from the mandatory standard clause to make them "intuitive," so the casual reader will have trouble understanding exactly what information should be filled in. Understanding the associated mandatory standard clause for each modifying clause will help to ensure time is not spent pursuing the wrong answers.

b. Assess

Purchasers must decide whether or not the mandatory standard clauses and proposed modifying clauses will adequately represent the procurement to be undertaken, and provide protections against substandard and possibly dangerous products. This is also the time to consider problems that might occur during bidding, evaluation, and contract performance. Additional clauses can be included, as long as they do not contradict the mandatory wording or the prevailing procurement regulations and guidelines. Purchasers must take care that the legal meaning of added and amended wording is clear and understood. The World Bank has suggested additional clauses for pharmaceuticals, vaccines, and condoms in its *Standard Bidding Document: Procurement of Health Sector Goods* and discusses some of the special considerations surrounding procurement of these items in its *Technical Note* document. Both are available on the World Bank website listed in Section I.3.a.

The next step is to make a list of information that needs to be filled in and decisions that must be made. Document "b" in Section I.2 may be helpful as a checklist. It is a listing of clauses in Special Instructions to Bidders and Special Conditions of Contract that require

input by the procuring entity. Information and decision requirements can then be separated into categories for inclusion of the following:

- Information that is obvious and can be filled in immediately, such as the purchaser's name and bid identification numbers.
- Information from the procurement planning and scheduling phase, such as quantities and delivery dates.
- Information that will need some investigation, such as information about ineligible countries and debarred firms.
- Decisions that will need to be made by the procuring entity, such as the minimum production capacity required for qualification, and whether or not there will be a pre-bid meeting.
- Decisions that should be made by others, particularly QA details and areas of government concern, such as domestic preference.[3]

c. Confirm Outside Services

In some less developed environments, it is also wise—at this point—to confirm the status of outside services and capabilities needed during procurement and contract performance. There may be problems associated with obtaining international services such as testing laboratories and preshipment inspection, or deficiencies in local capabilities (for example, banking)—particularly the ability to open commercial letters of credit (L/Cs). Ideally, these issues will be understood and steps will have been taken to correct the deficiencies before the procurement requisition is sent to the procurement unit. If this has not been done, the procurement unit should set any required processes in motion as soon as possible so that delays will not occur and the services are obtained within the time frame required.

2. Gathering Information and Making Decisions

Using the lists of information and decisions still needed, consider where and how these decisions might be obtained; for example, from the director, earlier bidding documents, the RH program manager, a calculation, a website, a consultant, a specification, the NRA, or the Ministry of Finance.

[3] **A price advantage is sometimes given to domestic firms during the selection process—used for comparison purposes only.**

Obviously, there are many decisions to be made, such as:

- Whether or not to charge a fee for bidding documents.
- Amount of bid security.
- Whether or not samples are required.
- Date and time for pre-bid meeting.
- Bid opening date and time; bid validity requirement.
- Whether or not bids will be accepted for less than the full quantity.
- Whether the price should be quoted as fixed.
- Whether and how domestic preference will be applied.
- What qualifications should be required.
- Whether evaluation will be on the basis of items or lots.

Some organizations develop standards for routine issues, such as the price of bidding documents. Fees may be appropriate for advertised open competitive bidding, and the price should not be so high as to eliminate competition. However, fees are not appropriate if the potential supplier has been asked directly to submit a bid.

Standards for this and other issues, such as commercial qualification criteria, can be an efficient time-saver.

3. Drafting the Bidding Documents

Now that information has been gathered and decisions made, it is time to draft wording for the different sections and put it all together into completed bidding documents.

Technical specifications and the schedule of requirements establish the "bones" of the procurement around which everything else will be built. These should be added first.

a. Technical Specifications

Detailed technical specifications written by qualified experts are provided to the procuring entity along with the official procurement requisition. Different items are included in the technical specifications, depending on the type of product to be purchased. Examples of contraceptive specifications can be found in Module 2.

b. Schedule of Requirements

Most of the information necessary for completing the Schedule of Requirements can be found in the procurement requisition (discussed in Modules 4 and 5). Document "c" in Section I.2 is a copy of the procurement requisition used as an example in earlier modules.

- The procurement office may need to write a short description of the goods—with just enough information to identify the product without confusion. (The Technical Specifications section provides a more detailed description.) For pharmaceuticals, including hormonal contraceptives, the international nonproprietary name or generic name should be mentioned, as well as the basic unit, package size, and the number of packages needed.
- ***Delivery schedule:*** The procurement requisition usually specifies the date that goods are required by the end user, but a different delivery date may need to be calculated for the bidding documents, one that takes into account the implications of INCOTERMS (explained in Module 4), such as CIP (meaning carriage [freight] and insurance costs are paid by the seller), that will apply to the procurement contract. Under some INCOTERMS, the goods are considered delivered when they are handed over to the carrier, not when they reach their final destination. If this is the case, the delivery date entered into the bidding documents should be earlier than the date the goods are needed in-country by the number of weeks estimated for shipping and clearing.
- The delivery date can be a specific month, day, and year, or a number of weeks after a stated event, such as after confirmation of an L/C. This is the place to indicate if the product is to be delivered in partial shipments and to outline the required schedule.

c. Special Instructions to Bidders

General and Special Instructions to Bidders establish **commitments** about how the purchaser will perform during the bidding, evaluation, and selection processes, as well as rules and requirements for potential bidders. The purchaser must insert three types of information into Special Instructions to Bidders:

- Routine administrative items, such as the name of the purchaser, how bidders should prepare and submit bids, and when and where bids will be opened.
- Eligibility and qualification requirements.

- Information that defines the purchaser's commitment to certain actions and decisions, such as validity periods, what is acceptable, what is not acceptable, how decisions will be made, and how bids will be handled.

The second and third bullet points represent areas in which protest, delays, and even cancellation of the bid can result if the procuring entity fails to abide by what it states in the bidding documents. Thus, it is very important for these sections to be clear and representative of what is actually going to happen. This can pose difficulties in systems that have recently adopted good public-sector procurement in principle but continue to follow outdated procedures.

d. Eligibility Criteria and Documents

Who can submit a bid? For most public-sector procurement, eligibility requirements are based on the country of manufacture, the country of the seller, and whether or not a firm has been debarred (Section D.2.c). Documentation requirements for eligibility amount to the firm not being on one of the lists of either excluded countries or debarred firms.

For health-sector procurement (pharmaceuticals, contraceptives, etc.), the goods themselves—not only the supplier of the goods—are required to meet eligibility criteria:

- A manufacturer's authorization letter (document "d" in Section I.2) is used to legally connect the bidder with the manufacturer of the offered products and to confer the manufacturer's basic responsibility for the goods, including warranty and guarantee. In health-sector procurement, it helps eliminate bids from middlemen who may knowingly deal in counterfeit, expired, or mislabeled products.
- Product licensing with the regulatory authorities of the purchaser's country and the manufacturer's country is treated as an eligibility requirement, reflecting the importance of this international practice. However, licensing in the purchaser's country is not always a prerequisite for bidding. Some countries allow the winning bidder to secure regulatory licensing for the offered product after the initial award, but delay contract signing until such licensing is in place. This strategy broadens the competition, but as a practical matter, it can lead to long delays in the procurement process because the regulatory licensing process often requires many months. Some countries have tried to solve this problem by setting time limits, after which, the contract would be awarded to the next lowest evaluated cost qualified bidder. Readers can see the possibility for manipulation in situations in which the local regulatory authority is operating on an agenda that runs counter to fair, competitive procurement. In countries where "fast-track" licensing is a possibility,

the risk of delay is significantly less. For additional information, see Supplementary Topics, Section K: Regulatory Authorities.

- Bidding documents must provide contact information for bidders to use to obtain additional information about requirements for registration of health-sector goods, but the documents themselves should not provide detail, since this could imply a commitment that the procuring entity is not at liberty to offer.
- In the event a purchasing country does not have a well-functioning regulatory authority set up to license pharmaceuticals and protect its population from substandard products, alternatives should be considered. For example, competition might be limited to products and manufacturers that are prequalified by WHO or are from countries with regulatory authorities belonging to the Pharmaceutical Inspection Co-operation Scheme[4] or the International Conference on Harmonisation.[5]

e. Qualification Criteria and Documents

Qualification criteria offer one of the best opportunities for RH purchasers to eliminate bids from sources that are likely to supply poor-quality products, miss delivery dates, or default on contract conditions.

Qualification of bidders can be done as a separate process prior to actual bidding (prequalification), or it can take place during the evaluation process, or it can be limited to the winning bidder (post-qualification). Prequalification is discussed in Section G. This segment will assume a cursory investigation at the evaluation stage and post-qualification of the winning bidder.

Regardless of when the investigation takes place, RH purchasers must determine if the bidder is qualified. Basic requirements are:

- Adequate production capacity and experience.
- Verifiable technical capability.
- Verifiable business and financial stability.
- History of successful performance.

[4] For more information, see http://www.picscheme.org/.

[5] International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use. For more information, see http://www.ich.org/cache/compo/276-254-1.html.

It is up to the procuring entity to develop *specific criteria* and to specify documentary evidence the bidder must submit. For example, in the case of production capacity, the procuring entity would define exactly how much capacity it considers "adequate" based on quantity and delivery time requirements of the subject procurement.

Defining evidence in support of specific criteria is not as clear-cut as defining the criteria itself. The purchaser might ask the bidder for a sworn statement of its installed manufacturing capacity and peak and average production over the past 3 years, but at evaluation, other details and documents submitted with the bid will be needed to corroborate bidder claims. The firm's financial information and audited financial statements, details of current commitments and contracts completed over the past several years, and the bidder's explicit permission for the purchaser to contact business and banking references are normally requested.

Guidance notes in the World Bank's *Standard Bidding Document: Procurement of Health Sector Goods* offer suggestions about appropriate qualification clauses. In addition, in 2002, the World Bank developed a trial edition, *Standard Prequalification Document: Procurement of Health Sector Goods*, which is still available on its website under electronic archives. Much of the same information can be found in the *Technical Note* attached to the *Standard Bidding Document*. (Websites are listed in Section I.3.a.)

Two clauses in the World Bank prequalification documents for health-sector goods are designed to provide an element of confidence in bidder statements with regard to their qualifications:

- Bidder's declaration: "The undersigned declare that the statements made and the information provided in the duly completed application are complete, true, and correct in every detail."
- Bidder's authorization: "Your agency and its authorized representatives are hereby authorized to conduct any inquiries or investigations to verify the statements, documents, and information submitted in connection with this [application], and to seek clarification from our bankers and clients regarding any financial and technical aspects. [This Letter of …] will also serve as authorization to any individual or authorized representative of any institution referred to in the supporting information to provide such information deemed necessary and as requested by yourselves to verify statements and information provided in this application, such as the resources, experience, and competence of the applicant."

Document "e" in Section I.2 is a synthesis of the qualification requirements published in the World Bank's prequalification document. Document "f" in Section I.2 is an expanded and more stringent set of qualification and documentation requirements obtained from a newly reformed public procurement system in South Asia. The terminology differs slightly: the word "tender" is used instead of the word "bid"; they are equivalent.

f. Evaluation Criteria

The word "evaluation" sometimes causes confusion because it is used broadly to describe the process of examining bids and more narrowly as a stage in the overall selection process. In order to reach the stage at which bids are evaluated in the narrower sense, they must first pass an initial examination and be deemed "substantially responsive" to the bidding documents—that is, they contain no major deviations (also called material deviations, and discussed in more detail in Module 7) from the specifications, expected contract language, or other requirements. Then price, price adjustments, and application of economic factors (nonfinancial items given a value) are evaluated.

Good public-sector bidding documents include complex fixed wording with regard to evaluation criteria; procuring entities need only "fill in the blanks." However, this seemingly simple task requires careful study and a full understanding of each fixed clause as well as the suggested fill-in options.

The procuring entity specifies what adjustments and economic factors will apply and explains how they will be calculated to arrive at an "evaluated price" for comparison with other bids.

- The "cross-discount" is an interesting example of a price adjustment. When allowed by the bidding documents, it lets bidders offer a discount based on award of more than one contract.
- Examples of "economic factors" include domestic preference, availability of local representation, and possibility of early delivery.[6] In these cases, a predetermined percentage is deducted from the offered price or added to competitor's prices to arrive at an amount for comparison (but not the price to be paid).

Evaluation criteria imply a commitment by the purchaser to choose a winning bid precisely as stated. If the purchaser deviates from this path, bidder protests, delayed procurement, or worse may result.

[6] The possibility of early delivery would also need to be mentioned in the Schedule of Requirements.

g. Currency of Bid

It is common to accept bids in any freely traded currency, so bidding documents must state what common currency will be used for evaluation and comparison purposes and exactly how currencies will be converted, including the source of the exchange rate and the date.

h. Bid Security

If bid security (defined in Section L) is required, it is always better to set the amount as a fixed number rather than a percentage of the bidder's offered price, in order to avoid premature disclosure. One to two percent of the budget estimate for the estimated contract is appropriate. Higher amounts may drive away potentially qualified bidders. A smaller amount, or even no bid security, is acceptable for simple contracts where the market is relatively stable and mature.

i. Validity Periods: Bids and Bid Security

In the bidding documents, the procuring entity informs prospective bidders how long after the deadline for bid submission their bids must remain valid. Normally expressed in days, a specific date should also be mentioned in order to eliminate errors in calculation or misunderstanding about the start and end dates. The number of days must be sufficient to permit the purchaser to complete the evaluation, obtain all necessary approvals, and issue the notification of award. In most cases, 90 days is adequate, but whatever period is selected, it must be realistic so that requests for extensions are kept to a minimum.

When bid security is required, an additional 28 days after the end of the bid validity period is commonly specified for the security to remain valid. A date should be mentioned here as well, because many bids are rejected on the basis of simple errors in calculating the bid security validity period.

If it becomes necessary to request extensions of bid validities, bid security extensions should be requested at the same time.

j. Deadline for Bid Submission

The date chosen for a bid submission deadline (for international bidding) is usually around 6 weeks from the date of issuance of the bidding documents, depending on the value, scope, and complexity of the goods being purchased.

k. Date and Time for Bid Opening

The date for bid opening should be the same as the bid submission deadline, and the time should be shortly thereafter to minimize possible complaints about insecure storage arrangements for the unopened bids.

l. Purchaser's Right to Vary Quantities at Time of Award

Allowing for a percentage increase or decrease in the contract amount is always a good idea. This provides an option other than canceling the bidding if prices offered exceed the available budget. On the other hand, if prices are lower than expected, the purchase of additional product might be attractive. The percentage should not be more than 20, and it must be mentioned in the bidding documents.

Quantity changes after the award has been made and accepted are handled via contract amendment, to which both parties must agree in writing. After a manufacturer has signed a contract and scheduled and committed resources based on that contract, it may be reluctant to accept sudden quantity changes. Thus, the possibility—if it exists—should be mentioned in the bidding documents' Special Conditions of Contract as a potential "change order."

m. Clarification of Bidding Documents

Proper communication with bidders is another area in which conflict can occur. All correspondence between potential (and actual) bidders and the procuring entity must be in writing, not verbal. The bidding documents provide an address and usually commit the purchaser to responding in writing to any request for clarification it receives no later than 14 calendar days prior to the deadline of submission of bids. Fixed wording also promises that copies of the response will be sent to all prospective bidders that have purchased the bidding documents, along with a description of the inquiry, but without identifying its source. A bidder that does not receive the same information as the others, and subsequently loses the contract, is likely to protest, leading to delays and possible cancellation of the bid.

n. Documents Comprising the Bid

Good public-sector bidding documents include a list of items the bidder must submit as its bid. The fixed clauses usually include the bid form, price schedule, evidence of bid security, written power of attorney authorizing the signatory of the bid to commit the bidder, documentary evidence of eligibility, documentary evidence that the goods to be supplied conform to the bidding documents, and documentary evidence that the bidder is qualified to

perform the contract. The purchaser must list what *specific* "documentary evidence" should be included.

o. Completion of Special Instructions to Bidders

Model bidding documents frequently include guidance notes and options in places where purchasers are expected to fill in particulars. When using an electronic copy of such a model, it is important to make sure all guidance notes and unused options are deleted once the necessary entries have been made. This step is frequently overlooked and produces confusion about exactly what is required.

p. Special Conditions of Contract

General and Special Conditions of Contract set rules and expectations about performance of the bidder and the purchaser after an award is made. Many of the clauses deal with routine contractual issues, such as definitions, performance security, liquidated damages, arbitration, and governing language. Local import practices and documentation requirements are reflected here as well; for example:

- Import licensing.
- General dockside sampling.
- Customs tariff and taxes.
- Commercial invoice.
- Shipping documents.
- Notifications.
- Receiving inspection and acceptance.
- Consular/customs invoice.

Special Conditions of Contract for routine and local requirements are often standardized by custom or dictated by a governing authority, so there is little for the RH purchaser to do but fill in the information. However, several areas (some of which are interrelated) require careful consideration and wording:

- Certification of goods (regulatory licensing and product registration).
- Inspections and tests.
- Packing and markings.
- Payment conditions and method of payment.

- Delivery and related documents.
- Warranty.

These areas are discussed below.

Certification of goods

This clause should mirror the information about regulatory licensing provided in the General and Special Instructions to Bidders. If the contract will not become effective until the product has been licensed by the regulatory authority of the purchaser's country, this is the place to set a time limit, from the date of contract signing, after which either party can declare the contract "null and void" by a written notice.

Inspections and tests

This clause should specify inspections and/or tests not otherwise mentioned in the standard documents and provide a cross-reference to corresponding requirements in the Schedule of Requirements and Technical Specifications. In the case of certain health-sector goods, preshipment inspection and sampling is conducted at the manufacturer's facility by an independent third party.[7] Testing, if required, is done at an independent laboratory before shipment. This is known as a "preshipment compliance program." It may include all or part of the following:

- Documentary review.
- Inspection at the manufacturer's facility.
- Sampling at the manufacturer's facility.
- Testing at an independent laboratory.

Preshipment compliance programs eliminate the time and trouble involved in returning goods and waiting for another shipment when substandard, poorly labeled, poorly packaged, or incorrect goods are detected. Their inclusion in a contract helps to deter intentional as well as accidental supply of substandard product.

In cases in which a stable, continuous flow of a specific commodity is a critical consideration (family planning, immunization, etc.), preshipment compliance programs are very important. Additional information on preshipment compliance programs can be found in Module 9. World Bank health-sector procurement documents provide sample wording for the Special Conditions of Contract with regard to inspection and testing of condoms.

[7] **There is potential risk associated with condoms in particular.**

Packing and markings

This clause is used to list requirements that are in addition to the General Conditions of Contract text. For example, the RH program 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 so they remain at less than a certain temperature, as is the case with vaccines and a few pharmaceuticals. This information must be cross-referenced to corresponding requirements in the Schedule of Requirements and Technical Specifications.

Payment conditions and method of payment

This clause is used to explain how and when payment will be made to the supplier. It is an important clause because it gives the purchaser an opportunity to build in tools for enforcing quality and timeliness requirements.

- Quality requirements can be enforced by requiring the supplier to present documents to the purchaser (or the paying bank) that give evidence of successful inspection and testing (when applicable).
- Shipping dates, documentation, notification, and marking requirements can be enforced by requiring evidence of compliance as a condition of payment.

When an L/C is used as the payment method, the bank will refuse to pay the beneficiary (in other words, the supplier) if it does not comply with the L/C conditions. Thus, the procuring entity must make sure that the L/C provisions reflect those stipulated in the Special Conditions of Contract.

An example of a payment clause can be found in Section I.2 as document "g." It demonstrates the level of detail required in good procurement documents.

Delivery and related documents

This clause is used to list documents the supplier must provide to the purchaser and/or a specified bank upon shipment. An example clause is provided in Section I.2 as document "h," but actual requirements differ from country to country.[8] Several types of documents are involved: normal commercial transport documents like the bill of lading, insurance certificate, and packing list; QA documents, such as the manufacturer's Certificate of Analysis and QA records; and regulatory documents, such as the lot release certificate issued by the regulatory authority of the manufacturer's country and the product approval

[8] **For example, some countries try to protect their local manufacturers from outside competition by requiring a No Objection Certificate from local producers of similar products.**

document (license, registration certificate, etc.) issued by the importing country's regulatory authority. These documents are used to:

- Clear the goods from customs (the legal requirements and procedures at the port of entry that allow goods to pass across the importing country's border).
- Establish conformity of the product to basic specifications (they should also appear in the corresponding specification).
- Establish proof of performance (this triggers payment to the supplier [by a bank in the case of an L/C]).
- Schedule inland transportation, receiving warehouse inspection, etc.

It is important to list exactly what documents will be required for entry into the purchaser's country.

If the proper documentation is not presented, the shipment can be held at the port, returned to the shipper, or destroyed. This is a good example of how a small oversight in the bidding documents can turn into a supply disaster.

Particular care should also be taken in specifying one of the normal transport documents: the clean, onboard bill of lading. If the L/C is going to require the seller to present an original, negotiable bill of lading to a specific bank for payment, then the contract clause about shipping documents should not require the seller to send it (the original, negotiable bill of lading) to the purchaser along with the other advance shipping documents. The purchaser will receive it from the commercial bank after the supplier is paid (see Supplementary Topics, Section C: Letters of Credit).

Finally, the procuring entity must be sure to state the number of originals and number of copies required for each document.

Warranty

There are four main warranty conditions for health-sector goods:

- Goods are of fresh manufacture and bear the dates of manufacture and expiry.
- All goods supplied under contract will have remaining a minimum of 5/6 of the specified shelf life upon delivery at the port of entry for goods with a shelf life of more than 2 years, and 3/4 for goods with a shelf life of 2 years or fewer, unless otherwise specified in the Special Conditions of Contract.

- Goods are not subject to recall by the applicable regulatory authority due to unacceptable quality or an adverse drug reaction.
- Purchaser shall have the right to make claims under the warranty for 3 months after the goods have been delivered to the final destination indicated in the contract.

Depending on the contract form, these conditions may appear in the General or Special Conditions of Contract. If they are included in the General Conditions of Contract, the purchaser would use the Special Conditions of Contract to alter times and numbers.

q. Completion of Special Conditions of Contract Clauses

As the reader can see by now, there is an important interrelationship between clauses on certification of goods, inspections and tests, payment, and delivery and documents that together provide for enforcement of quality and timeliness requirements. In addition to coordinating this foundation, the procuring entity should make sure that treatment of each issue in the Special Conditions of Contract is consistent with wording in the corresponding Special Instructions to Bidders, Schedule of Requirements, and Technical Specifications.

4. Preparing the Documents for Sale or Distribution

When all required entries have been made and all superfluous text has been deleted, the procuring entity compiles the various parts into a bidding document package, applies page numbers, and constructs a table of contents and a title page. A suggested table of contents would include:

- General Instructions to Bidders.
- Special Instructions to Bidders.
- Schedule of Requirements.
- Technical Specifications.
- Eligibility and Qualification Criteria.
- General Conditions of Contract.
- Special Conditions of Contract.
- Forms [to be used by the bidder].

a. Review of Documents and Caution

Outside review of bidding documents is recommended. In addition, many organizations, funders, and government entities wish to review and approve draft bidding documents before they are made available to the public.

As a result of review, changes or corrections may be required. These should be undertaken with great care and acumen, as it is easy to ruin an otherwise good document by forgetting to make corresponding changes in other sections. Sometimes only a word or two will be affected. At other times, the entire meaning of a clause will be altered, with far-reaching implications for processes or requirements.

F. Inviting and Receiving Bids

1. Bidding Document Sets and Document Register

As soon as all approvals are in place, the procuring entity can begin preparing document sets for distribution to interested parties. The number of sets that should be produced depends on the type of goods, the approximate number of prospective bidders, the source of goods (national or international), and previous sales of bidding documents for similar goods. Additional sets are normally produced for official purposes.

Each set of documents should be numbered and a register set up to record the names, addressees, and document numbers of all bidders, so they can be informed about any pre-bid conferences, amendments to the documents, or other official business.

2. Invitation for Bids and Transmittal of Bidding Documents

When the documents are ready for issue, the procuring entity can begin soliciting bids by extending a public Invitation for Bids to all interested firms and parties. This is done through advertising in newspapers, official gazettes, specialized journals (in the case of very large values), on organizational and/or governmental websites, and on local bulletin boards. In addition to advertisements and website notices, the procuring entity may want to send notices directly to suppliers it hopes to attract. Notices *must* be sent to suppliers that have expressed an interest as a result of preliminary general procurement notices. The objective is to reach as many prospective bidders as possible.

Another means of issuing an Invitation for Bids and soliciting responses from bidders is through e-bidding. e-Bidding is one component of the larger e-procurement process that is becoming more commonly used in procurement practices. Since bidding requires special software and functioning Internet technology, which is often not available on a consistent basis to many public-sector procuring entities in developing countries, in this section, we will focus on the traditional practices for issuing an Invitation for Bids. See Supplementary Topics, Section B: e-Procurement, for more information.

The Invitation for Bids notice very briefly describes the procurement requirements and provides prospective bidders with information on where and how they can obtain bidding

documents. Many purchasing organizations have standard formats and templates for this notice. Document "i" in Section I.2 is an example of a hard-copy format suitable for print.[9]

Large contracts for RH supplies, particularly contraceptives, will almost always attract interest from international sources, so a facility for transmitting bidding documents outside the country is necessary. If the purchasing country lacks reliable mail service, an alternate method must be arranged, possibly a courier or express document service. Unimpeded access to funds for postage or courier fees to deliver bidding documents to interested parties is a critical prerequisite for international competitive bidding.

When the documents and Invitation for Bids are ready, and the facility for transmitting bidding documents to prospective bidders has been assured, the RH purchaser can place the advertisements and the website notices. These should appear at the same time.

3. Pre-bid Conference (optional)

Pre-bid meetings of prospective suppliers are held for international and important local procurements, when it is thought necessary. At these meetings, questions are answered and minutes are recorded. If a question or concern cannot be answered during the meeting, it is referred to an appropriate expert.

In a highly competitive situation, pre-bid meetings can become difficult to control, so it is very important to set a firm agenda and make an advanced plan for managing the flow of questions and answers. Procedural errors during the meeting, or in writing or distributing the minutes, can result in official protests by competing bidders, which will almost certainly delay the procurement process.

a. Meeting Arrangements

Any pre-bid conference should take place well ahead of the bid opening date. The procuring entity should arrange a convenient place and time for the conference. The room must be large enough to hold at least:

- Two representatives from every intending and prospective bidder.
- All officers and directors who had a significant role in developing or approving the draft bidding documents.

[9] **From the World Bank's *Standard Bidding Document: Procurement of Health Sector Goods.***

- Appropriate procurement office staff and their directors.
- A representative of the funding organization as appropriate.

b. Notification of Prospective Bidders

A notice about the conference should be given to the prospective bidders at the time they purchase the bidding documents. All prospective bidders up through the last one to purchase documents before the pre-bid conference should receive this notice.

c. Attendance

Participation should be limited to parties that have purchased bidding documents. Those attending should be registered and an attendance list generated, including titles and contact information.

d. Responding to Questions

The answers provided to questions asked during the pre-bid conference should be only to clarify an aspect of the bidding documents. It is important to not expand or modify the information stated in the bidding documents when providing an answer. If a question or concern cannot be answered during the pre-bid conference, it is referred to an appropriate expert. All questions and answers are documented and provided in writing to all bidders after the pre-bid conference.

e. Distribution of Minutes and Post-meeting Announcements

Each recipient of the original bidding documents should be provided a copy of the minutes and any deferred answer in sufficient time before the submission deadline to enable appropriate actions.

Bidding documents may need to be amended as a result of questions and issues that are brought up by registered participants. If this happens, it will probably be necessary to extend the bid submission period as well. In the case of amended documents, the procuring entity should:

- Notify directly the prospective bidders that purchased bidding documents.
- Place notification of the extension on the website(s) where the original Invitation for Bids first appeared.
- If there is sufficient time, also place the notification in appropriate newspapers and publications.

4. Additional Preparation

Three additional preparation steps are necessary:

- Arranging a secure location to hold bids prior to opening.
- Setting up a system for handling funds collected from prospective bidders for the cost of the bidding documents.
- Setting up a system for safeguarding bid securities after bids have been opened.

5. Receiving and Managing Bids

Basic rules for receiving and managing bids:

- Bids must be held unopened until the stated day and time of bid opening.
- Bid envelopes should be stamped with the date and time they are received.
- Except for questions and answers in writing to/from the procuring entity, no one associated with the procurement is permitted to communicate with bidders regarding the bid from the time the advertisement appears until after an award has been made.

G. Prequalification: Issues and Documents

1. Issues

Procuring entities sometimes choose to limit competition for contract awards to a list of potential bidders and products they have prescreened and approved through a prequalification process. This involves advertising the opportunity to prequalify and providing a set of documents to applicants that establishes rules and requirements, as well as evaluating every application. In addition, WHO's Prequalification of Medicines Programme[10] results in a list of prequalified products and manufacturers. For more information, see Supplementary Topics, Section E: Prequalification.

Prequalification focuses on two separate aspects of the selection process:

- Quality, safety, and efficacy of the **product**.
- Reliability of the **supplier**.

In countries with weak regulatory systems, prequalification can be a valuable tool for helping to ensure product quality as well as reliability of the supplier. In countries with satisfactory regulatory systems, prequalification tends to focus more on supplier reliability.

Prequalification may be an attractive time-saver in situations in which a large number of bids from questionable sources are routinely received. It may be less so for procurement that attracts bids from smaller, more regulated markets.

Curative pharmaceuticals are produced by many manufacturing firms in nearly every country in the world, and open tenders can result in an excess of questionable offers. In small countries with weak regulatory systems, prequalification can be used to develop a core of reliable suppliers of quality products from which to draw repeatedly.

The hormonal contraceptive marketplace is much smaller than the general pharmaceutical marketplace, and it is dominated by products that have been licensed by stringent regulatory authorities such as those belonging to the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme and the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use. In addition, WHO recently added hormonal contraceptives to its prequalification project and will soon make available on their website lists of products they have investigated

[10] For more information, see http://apps.who.int/prequal/.

and accepted. Thus, reliability of the supplier rather than quality of the product would be the most likely focus of prequalification.

The condom marketplace is not large in comparison to general pharmaceuticals, but it has a history of quality issues. Condom production derives from a nonpharmaceutical environment, and, until the 1990's, many NRAs did not regulate or license this product. In 1989, WHO began providing guidance for condom purchasers. The most recent WHO guidance on condom procurement can be found in the document, *The Male Latex Condom: Specification and Guidelines for Condom Procurement* (2003). The United Nations Population Fund (UNFPA) employs a prequalification program for condom manufacturers, and procures condoms only from those manufacturers that meet the prequalification requirements. UNFPA is collaborating with WHO to harmonize the UNFPA prequalification process for condoms and intrauterine devices with WHO's prequalification process for medicines. Updated specifications and guidelines for procurement of these two contraceptives will be posted on the WHO and UNFPA websites upon completion. The application of solid specifications and the use of prequalification systems have improved the quality of condoms over the past 15 years.

RH purchasers should consider their product profiles, the availability of suppliers prequalified by WHO, the size of the marketplace, and their own objectives in deciding whether or not to prequalify suppliers.

2. Documents

Two different sets of prequalification documents available on organizational websites are listed in Section I.3. One focuses on product quality, the other on supplier reliability.

- ***Quality focus:*** *Practical Guidelines on Pharmaceutical Procurement for Countries with Small Procurement Agencies*; *Attachment 1: Model Questionnaire for Prequalification of Suppliers* (WHO Regional Office for the Western Pacific, 2002) (Section I.3.b).
- ***Reliability focus:*** *Standard Prequalification Document: Procurement of Health Sector Goods*, Trial Edition (World Bank, 2002) (Section I.3.a).[11]

Readers who have turned directly to this section should be sure to read the Sections D.2.i, Qualification Criteria, and E.3.e, Qualification Criteria and Documents.

[11] **Also see the "Bidder Information Form" in the World Bank's *Standard Bidding Document: Procurement of Health Sector Goods*.**

H. Request for Quotation: Issues and Documents

For small-quantity or low-value procurement, the cost of formal competitive bidding may outweigh the advantages. A Request for Quotation containing the description and quantity of the goods required and the desired delivery time and place is sent to a minimum of three potential suppliers (to ensure competitive prices). Instructions for response and a copy of the expected contract terms and conditions are included as well. Offers can be opened and reviewed as they arrive or held until a specified opening date. If permitted by the purchasing authority, a period of discussion and negotiation may follow.

A sample Request for Quotation can be found in Section I.2 as document "j." A simplified version is provided as document "k."

I. Reference Material

1. Checklists and Forms

Documents "a" and "b" can be used as checklists by the purchaser.

2. Documents

a. Mandatory Standard Clauses for Bidding Documents

General Instructions to Bidders	
Scope of Bid	
Source of Funds	
Fraud and Corruption	
Eligibility	
Eligible Goods and Services	
Documents Establishing Eligibility of Goods and Services and Conformity to Bidding Documents	
Qualifications of the Bidder	
One Bid per Bidder	
Cost of Bidding	
Content of Bidding Documents	
Clarification of Bidding Documents	
Amendment of Bidding Documents	
Language of Bid	
Documents Constituting the Bid	
Bid Form	
Bid Prices	
Currencies of Bid	
Bid Security	
Period of Validity of Bids	
Alternative Bids by Bidders	
Format and Signing of Bid	
Sealing and Marking of Bids	
Deadline for Submission of Bids	
Late Bids	
Modification and Withdrawal of Bids	
Bid Opening	
Confidentiality	
Clarification of Bids	
Examination of Bids and Determination of Responsiveness	
Correction of Errors	
Conversion to Single Currency	
Evaluation and Comparison of Bids	
Domestic Preference	
Post-qualification	
Award Criteria	
Purchaser's Right to Vary Quantities at Time of Award	

Purchaser's Right to Accept Any Bid and to Reject Any or All Bids	
Notification of Award	
Signing of Contract	
Performance Security	

General Conditions of Contract	
Definitions	
Application	
Contract Documents	
Corrupt, Fraudulent, Collusive, or Coercive Practices	
Country of Origin	
Specifications and Standards	
Interpretation	
Documents Forming the Contract and Priority	
Use of Contract Documents and Information	
Inspection and Audit	
Eligibility	
Gratuities and Agency Fees	
Joint Venture	
Confidential Information	
Certification of Goods in Accordance with Laws of the Purchaser's Country	
Patent and Intellectual Property Rights	
Copyright	
Supplier's Responsibilities	
Purchaser's Responsibilities	
Scope of Supply	
Performance Security	
Inspections and Tests	
Packing and Documents	
Delivery and Documents	
Acceptance	
Insurance	
Transportation	
Incidental Services	
Warranty	
Terms of Payment	
Prices	
Change Orders and Contract Amendments	
Assignment	
Subcontracts	
Delays in the Supplier's Performance	
Extensions of Time	
Liquidated Damages	
Force Majeure	
Termination for Insolvency	
Termination	
Resolution of Disputes	
Limitation of Liability	
Governing Language	
Applicable Law	

Notices and Communications	
Taxes and Duties	
Changes in Laws and Regulations	
Clauses Requiring User Input	

b. Modifying Clauses for Bidding

Bid Data Sheet (Special Instructions to Bidders)	
General Clauses:	
Name of Purchaser	
Name of Borrower	
Procurement Guidelines	
Eligibility Documentation	
Registration Requirements	
Qualification Criteria	
Bidding Documents:	
Purchaser's Contact Information	
Preparation of Bid:	
Language Requirements	
Documents Required to be Submitted with Bid	
Place of Destination per INCOTERM Used	
Final Destination of Goods	
Submission Price in xx INCOTERM in Addition to CIP	
Prices Fixed for Duration, or Adjustable	
Percentage of Items Required for Each Lot; Items of Lot	
Currency Used	
Bid Validity Period	
Bid Security	
Alternative Bids	
Number of Copies of Bid to be Submitted in Addition to Original	
Submission of Bid:	
Option of Submitting Bids Electronically	
Purchaser's Address for Bid Submission Purposes	
Marks for Bid Submission Envelopes	
Deadline for Bid Submission	
Opening and Evaluation of Bids:	
Bid Opening Time and Place	
Factors for Evaluation	
Conversion of Bid Prices to Single Currency	
Delivery Schedule and Late Deliveries	
Deviations in the Payment Schedule	
Domestic Preference	
Award of Contract:	
Maximum Percentage for Item Quantity Increase/Decrease	
Post-qualification	

Special Conditions of Contract	
Nature of Goods to be Supplied	
Purchaser's Country	
Purchaser's Name, Address, etc.	
Project Site/Final Destination	
End User	
Applicability	
Applicable Edition of INCOTERMS	
Supplier's Name, Address, etc.	
Documents That Are Also Part of the Contract	
Registration of Goods and Other Certification	
Ineligible Countries for Suppliers and Subcontractors	
Ineligible Countries for Goods and Related Services	
Standards	
Assignment	
Language	
Purchaser's and Supplier's Contact Information for Notices	
Governing Law, Language	
Patent Rights	
Packing List Requirements	
Packing, Markings, Documentation	
Details of Shipping and Other Documents to be Furnished by Supplier	
Prices Subject to Adjustment or Not	
Incidental Services	
Change Orders and Contract Amendments	
Method and Conditions of Payment	
Penalty for Late Payment by Purchaser	
Insurance Coverage Requirements	
Transport of Goods	
Performance Security	
Inspections and Tests	
Warranty Period	
Repair/Replacement Period	
Delays in Supplier's Performance	
Liquidated Damages' Percentage and Maximum	
Termination	
Force Majeure	
Arbitration Place/Rules	
Limitation of Liability	
Taxes and Duties	

These clause references were taken from the World Bank's *Standard Bidding Document: Procurement of Health Sector Goods*. The complete verbiage for each clause can be found on the World Bank website at http://web.worldbank.org/WBSITE/EXTERNAL/PROJECTS/PROCUREMENT/0,,contentMDK:21890171~menuPK:84284~pagePK:84269~piPK:60001558~theSitePK:84266~isCURL:Y,00.html.

c. Example Procurement Requisition

PROCUREMENT REQUISITION

To:

Program Submitted By:

Date:

Program Contact Person:

Program Contact's Telephone, Fax, Email:

Item:

Product Name	ID #	Unit	Unit of Measure	Quantity	Reference Price*	Total Cost

*with freight, fees, taxes

1. **Item Description:** *[short version]*

   Full Technical Specification Attached: Yes No *[circle one]*
   If "No," current disposition and date expected:

   Estimated Weight/Dimensions /100 Units:

   Import License Required: Yes No *[circle one]*

2. **Quality Assurance Provisions:**

   WHO Prequalification Required? Yes No *[circle one]*
   Preshipment Inspection Required? Yes No *[circle one]*
   Preshipment Testing Required? Yes No *[circle one]*
   Regulatory Licensing Required? Yes No *[circle one]*

3. **Delivery Schedule:**

   Number of Deliveries: ____

	Date	Quantity	Location/Ultimate Consignee
1.			
2.			
3.			

   Partial Shipments Allowed? Yes No *[circle one]*

4. **Shipping Instructions:**

   Ship To:
   Ship Via:
   Special Handling Requirements:
   Shipping Marks:
   Notify Party and Contact Information:

5. **Payment Terms Authorized:** *[circle one or more]*

   Letter of Credit (open at xxx bank) Open Account

   Cash in Advance (United Nations agency only) Down Payment

   Other *[explain]*:

6. **Preferred Delivery Terms:** *[INCOTERM]*

7. **Procurement Options Authorized:** *[circle one or more]*

   Competitive Bidding United Nations Agency

   Catalog Supply Service Other *[explain]*

8. **Source of Funding:**
   Applicable Regulations/Guidelines:

9. **Foreign Exchange Available?** Yes No *[circle one]*

10. **Special Instructions:**
    [*Example:*
    Submit bidding document draft to xxxx for approval prior to release
    Contract to allow +/- 10 percent quantity fluctuation]

_____

Procurement authorized by: _____ **Date:** _____

Authorizing signature: _____

d. Example Manufacturer's Authorization

Example Manufacturer's Authorization

[The bidder shall require the manufacturer to fill in this form in accordance with the instructions indicated. This letter of authorization should be on the letterhead of the manufacturer and should be signed by a person with the proper authority to sign documents that are binding on the manufacturer. The bidder shall include it in its bid, if so indicated in the Bid Data Sheet.]

Date: *[insert: **date** (day, month, and year) **of bid submission**]*

International Competitive Bidding No.: *[insert: **bidding process number**]*

Alternative No.: *[insert: **identification number if this is a bid for an alternative**]*

To: *[insert: **complete name of purchaser**]*

WHEREAS

We, *[insert: **complete name of manufacturer**]*, the official manufacturer of *[insert: **type of goods manufactured**]*, having factories at *[insert: **full address(es) of manufacturer's factory(ies)**]*, do hereby authorize *[insert: **complete name of bidder**]* to submit a bid the purpose of which is to provide the following goods, manufactured by us, *[insert: **name and/or brief description of the goods**]*, and to subsequently negotiate and sign the contract.

We hereby extend our full guarantee and warranty in accordance with Clause 27 of the General Conditions of Contract with respect to the goods offered by the above firm.

Signed: *[insert: **signature(s) of authorized representative(s) of the manufacturer**]*

Name(s): *[insert: **complete name(s) of authorized representative(s) of the manufacturer**]*
Title(s): *[insert: **title(s)**]*

Duly authorized to sign this Authorization on behalf of: *[insert: **complete name of bidder**]*

Dated on _____ day of _____, _____ *[insert: **date of signing**]*

e. Example Qualification Requirements

Example Qualification Requirements

Documentary evidence in case of bidder offering to supply goods under the contract that the bidder manufactures or otherwise produces (using ingredients supplied by primary manufacturers) that the bidder is:

Incorporated in the country of manufacture of the goods.

Has been licensed by the regulatory authority in the country of manufacture to supply the goods.

Has received a satisfactory current good manufacturing practices inspection certificate in line with the World Health Organization Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce from the regulatory authority in the country of manufacture of the goods, or has been certified by the competent authority of a member country of the Pharmaceutical Inspection Co-operation Scheme, and has demonstrated compliance with the quality standards during the past two (2) years prior to bid submission.

Has manufactured and marketed the specific goods covered by these bidding documents for at least two (2) years, and for similar goods, for at least five (5) years.

That, in the case of a bidder offering to supply goods under the contract that the bidder does not manufacture or otherwise produce, the bidder has been duly authorized by a manufacturer of the goods that meets the above criteria to supply the goods in the purchaser's country.

The bidder shall also submit the following additional information:

A statement of installed manufacturing capacity.

Copies of audited financial statements for the past three (3) fiscal years.

Details of onsite quality control laboratory facilities and services and range of tests conducted.

List of major supply contracts conducted within the last five (5) years; names of countries to which applicant has supplied products worth at least the amount specified (US$xxx) within the last three (3) years.

Evidence that it has the financial, technical, and production capability necessary to perform the contract:

(A) That it has successfully completed or substantially completed at least xxx (not fewer than three and not more than five) similar contracts for supply of the goods within the last xx years (similar contracts are those of approximately the same size and that include comparable products).
(B) That it has achieved an annual production rate of xx (at least three times the quantities specified under the contract).
(C) That it has generated an average annual turnover (annual sales value) at least five times the estimated contract value during the last five (5) years.

f. Alternate Example Qualification Requirements (extended)

Regulation 12—Qualification of Bidder

In order to participate in public procurement, bidders shall provide evidence to demonstrate that they are suitably qualified. The purpose of qualification is to ensure that:

- Those persons or firms participating in public procurement are able to meet the professional and ethical standards set out in the regulations and the procedures.
- Suppliers, contractors, and consultants are able to perform the contracts for which they are bidding or offering services.

The requirements for such qualification as set out in the regulations are detailed in the following paragraphs:

(a) Professional and Technical Capacity:
Suppliers, contractors, and consultants shall show that they possess:

- The professional and technical qualifications and experience to undertake the work/supply/service for which they are bidding.
- Satisfactory financial resources.
- Suitable equipment and other physical facilities or proven access through contractual arrangement to hire/lease such equipment/facilities for the desired period, where necessary.
- Satisfactory production/manufacturing capacity, where necessary.
- After-sales service, where necessary.
- Managerial capability, where necessary.
- Prior experience of the work/supply/service for which they are bidding.
- Satisfactory reputation for diligent and nonproblematic performance of contracts (repeated arbitration or legal proceedings against the bidder taint its reputation).
- Appropriate personnel required to perform the contract, both in terms of numbers and skills.

(b) Legal Capacity:
Suppliers, contractors, and consultants shall show that they are legally entitled to enter into any subsequent contract that might arise from the procurement proceedings. This means that persons and/or firms shall demonstrate to the procuring entity that there is no legal reason (e.g., an order of a judicial court) that prevents them from entering into a contract. (Such a reason might be that a privately owned company was bankrupt, and as a result, the person owning the company and the company itself were banned by a court from entering into any contract.)

(c) Financial Capability and Status:
Suppliers, contractors, and consultants shall show that they are not:

- Insolvent (e.g., the person or firm is not financially capable to perform the contract for which they are bidding).
- In receivership (e.g., the firm was in serious financial difficulties and a court had, at the request of creditors, stopped the firm from managing itself and had placed an independent accountant in charge of the company's business operations).
- Bankrupt or in the process of being wound up (e.g., the person or firm's financial situation is that they have more debts than income and can no longer function).

- Suspended from undertaking their business for financial reasons.
- Subject to legal proceedings for any of the above reasons/grounds.

(d) Taxation Obligations:
Suppliers, contractors, and consultants shall show that they have fulfilled their obligations to pay taxes and social security obligations under the relevant national regulations (e.g., a surcharge or a tax for creating public utilities, disability surcharge, etc.). Documentary evidence to be provided by a foreign bidder to demonstrate that it meets these criteria may consist of a written declaration to that effect by the bidder.

Based on the above four general qualification criteria and the nature and magnitude of the object of particular procurement, procuring entities shall set out specific qualifications in the prequalification document, bidding documents, or Request for Proposal document.

In order to verify that a potential supplier, contractor, or consultant meets the requirements specified above, the procuring entity may require submission by the bidder of documentary evidence or other information from an appropriate authority or organization that shows the potential supplier, contractor, or consultant meets these requirements.

The following paragraphs detail the documentation that may be requested by the procuring entity from the bidder:

(e) Professional and Technical Capacity:
- Evidence to show the bidder is enrolled in the relevant professional or trade organizations registered in the procuring entity's country or in its country of origin or to provide a declaration on oath or a certificate concerning its competency in accordance with the conditions laid down by the law of the procuring entity's country or of the country of its origin (such an oath or certificate would, normally, be provided by a professional institution related to the professional qualifications of the person or firm).
- A description of the firm's technical facilities, its available equipment, its measures for ensuring quality (e.g., ISO certification), and its design, research, and development facilities.
- A list of the major deliveries effected in the past three (3) to five (5) years, with the sums, dates, and recipients, public or private, on a transaction basis, if a procuring entity so requests.
- A list of client references that may be contacted by the procuring entity.
- Samples, description, and/or photographs of the product to be supplied, the authenticity of which may be certified by a professional institution related to the professional qualifications of the person or firm, if the procuring entity so requests.
- Appropriate statements from bankers of the firm's financial resources.
- The firm's balance sheets or extracts from them, where publication of a balance sheet is required under company law in the country in which the supplier, contractor, or consultant is established.
- Statement of the firm's overall turnover and its turnover in respect of the goods/works/services to which the contract relates for the previous three (3) financial years.
- Details of the numbers of both technical and administrative personnel employed by the firm.

(f) Legal Capacity:
The legal capacity shall be confirmed by a power of attorney. This document shall state that there are no existing orders of any judicial court that prevent either a person or firm or employees of a firm from entering into and/or signing a contract with the procuring entity.

(g) Financial Status:
If the procuring entity so requests, it is for the applicant or bidder to prove that none of those circumstances apply (described in Section c above). Proof can be provided in the form of a document issued by an appropriate authority in the country of the procuring entity or in the country of the bidder, showing that none of these cases apply.

(h) Taxation Obligations:
For proof of fulfillment of obligations relating to the payment of taxes and social security contributions, the procuring entity may ask the bidder or applicant for a certificate issued by the competent authority of the procuring entity's country, or in the case of foreign bidders, from the competent authority in that country. The tax certificate shall state:

- Tax registration number or taxpayer's identification number.
- Value added tax registration number.
- The year up to which income tax/value added tax assessment has been completed.
- Confirmation that tax/value added tax has been paid regularly.

It shall be noted that the above requirements represent the minimum qualification requirements. However, procuring entities may need to add to or amend these requirements for specific bids.

g. Example Payment Clause

Example Payment Clause

The method and conditions of payment to be made to the supplier under this contract shall be as follows:

Payment for goods supplied from abroad

Payment of foreign currency portion shall be made in *[insert currency of the contract price]* in the following manner:

- Advance payment: Ten (10) percent of the contract price shall be paid within thirty (30) days of signature of contract and receipt of the performance guarantee, upon submission of an invoice (showing purchaser's name; the contract number; [loan number if applicable]; description of payment; and total amount, signed in original, stamped or sealed with the company stamp/seal) and a bank guarantee in the form provided in *[Section xxx]*, Advance Payment Bank Guarantee.
- On shipment: Eighty (80) percent of the contract price of the goods shipped shall be paid through irrevocable confirmed letter of credit opened in favor of the supplier in a bank in its country, upon submission of documents specified in General Conditions of Contract Clause 11, or, alternatively, at the supplier's option, within thirty (30) days of submission of documents specified in General Conditions of Contract Clause 11 above by direct bank transfer to the supplier's nominated bank account. Opening changes and charges for amendment of the letter of credit at the request of or due to a fault or default of the purchaser are for the account of the purchaser. Confirmation charges and charges for amendment to letters of credit at the request of or due to a fault or default on behalf of the supplier are for the account of the supplier.
- On acceptance: Ten (10) percent of the contract price of goods received shall be paid within thirty (30) days of receipt of the goods upon submission of an invoice (showing purchaser's name; the contract number; [loan number if applicable]; description of payment; and total amount, signed in original, stamped or sealed with the company stamp/seal) supported by the Certificate of Acceptance issued by the purchaser.

Payment of the local currency portion shall be made in *[insert currency]* within thirty (30) days of presentation of an invoice (showing purchaser's name; the contract number; [loan number if applicable]; description of payment; and total amount, signed in original, stamped or sealed with the company stamp/seal) supported by the Certificate of Acceptance issued by the purchaser.

h. Example Delivery and Documents Clause

Example Delivery and Documents Clause

For goods supplied from abroad

Upon shipment, the supplier shall notify the purchaser and the insurance company in writing of the full details of the shipment, including contract number, description of the goods, quantity, date and place of shipment, mode of transportation, and estimated date of arrival at the place of destination. In the event of goods sent air freight, the supplier shall notify the purchaser a minimum of forty-eight (48) hours ahead of dispatch, the name of the carrier, the flight number, the expected time of arrival, and the air waybill number. The supplier shall fax and then send by courier the following documents to the purchaser, with a copy to the insurance company:

- Three originals and two copies of the supplier's invoice, showing purchaser as *[enter correct description of purchaser for customs purposes]*, the contract number, [loan number if applicable], goods description, quantity, unit price, and total amount. Invoices must be signed in original and stamped or sealed with the company stamp/seal.
- One original and two copies of the negotiable, clean, onboard bill of lading marked "freight prepaid" and showing purchaser as *[enter correct name of purchaser for customs purposes]* and Notify Party as stated in the contract, with delivery through to final destination as per the Schedule of Requirements, and two copies of the nonnegotiable bill of lading, or three copies of the railway consignment note, road consignment note, truck or air waybill, or multimodal transport document, marked "freight prepaid" and showing delivery through to final destination as per the Schedule of Requirements.
- Four copies of the packing list, identifying the contents of each package.
- Copy of the insurance certificate, showing the purchaser as the beneficiary.
- One original of the manufacturer's or supplier's warranty certificate, covering all items supplied.
- One original of the supplier's Certificate of Origin, covering all items supplied.
- Original and six copies of the Certificate of Inspection furnished to supplier by the nominated inspection agency (when inspection is required).
- Any other procurement-specific documents required for delivery/payment purposes.

Additional clause for pharmaceuticals:

For goods supplied from abroad

- One original of the Certificate of Pharmaceutical Product as recommended by the World Health Organization for each of the items supplied.
- Certificate of quality control test results in conformity with the World Health Organization Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce, stating quantitative assays, chemical analysis, sterility, pyrogen content, uniformity, microbial limit, and other tests as appropriate to the goods.
- Original and six copies of the Certificate of Weight issued by the port authority/licensed authority.

Additional clause for condoms:

For goods supplied from abroad

- Original copy of quality control tests for each consignment as stated in the Special Conditions of Contract, Clause xx.
- Original and six copies of the Certificate of Inspection furnished to the supplier by the nominated inspection agency.

i. Example Invitation for Bids

Example Invitation for Bids

*[insert: **name of country**]*

*[insert: **name of project**]*

*[insert: **brief description of the goods**]*

*[insert: **loan/credit number**]*

*[insert: **Invitation for Bids title**]*

*[insert: **Invitation for Bids number**]*

1. This Invitation for Bids follows the general procurement notice for this project that appeared in *Development Business*, issue no. *[insert number]* of *[insert date]*.
2. The *[insert name of borrower] [has received/has applied for/intends to apply for]* a *[loan/credit]* from the *[International Bank for Reconstruction and Development/International Development Association]* toward the cost of *[insert name of project]*, and it intends to apply part of the proceeds of this *[loan/credit]* to payments under the contract for *[insert name/no. of contract].*
3. The *[insert name of implementing agency]* now invites sealed bids from eligible bidders for *[insert brief description of goods or works to be procured]*.
4. Bidding will be conducted through the international competitive bidding procedures specified in the World Bank's *Guidelines—Procurement Under IBRD [International Bank for Reconstruction and Development] Loans and IDA [Foundation] Credits*,[12] and is open to all bidders from eligible source countries as defined in the *Guidelines*.
5. Interested eligible bidders may obtain further information from *[insert name of agency]* and inspect the bidding documents at the address given below *[state address at end of document]* from *[insert office hours]*.
6. A complete set of bidding documents in *[insert name of language]* may be purchased by interested bidders upon the submission of a written application to the address below *[state address at the end of document]* and upon payment of a nonrefundable fee of *[insert amount in local currency]* or of *[insert amount in specified convertible currency]*. The method of payment will be *[insert method of payment]*. The document will be sent by *[insert delivery procedure]*.
7. Bids must be delivered to the address below *[state address at the end of document]* at or before *[insert time and date]*. If required, all bids must be accompanied by a bid security of *[insert amount in local currency or minimum percentage of bid price]* or an equivalent amount in a freely convertible currency. Late bids will be rejected. Bids will be opened in

[12] **Available at: http://siteresources.worldbank.org/INTPROCUREMENT/Resources/Procurement-May-2004.pdf.**

the presence of the bidders' representatives who choose to attend at the address below *[state address at end of document]* at *[insert time and date]*.

*[insert: **name of office**]*

*[insert: **name of officer**]*

*[insert: **postal address**] and/or*

*[insert: **street address**]*

*[insert: **telephone number, indicate country and city code**]*

*[insert: **facsimile or cable number or email address**]*

j. Example Request for Quotation

Example Request for Quotation

[Letterhead of procuring entity]

To: Date:

From:

REQUEST FOR QUOTATION [reference number]

The Reproductive Health Program of [agency, ministry, country] requests your quotation or proposal of price and availability for any or all of the items and quantities shown in Annex One. Specifications for the items known to match your product line appear in Annex Two. The [procuring entity] will provide its procurement specification for any of the remaining items upon your request.

Contracts are expected to be signed during [date or quarter of year], with initial deliveries commencing immediately thereafter. Payment terms are negotiable or by irrevocable letter of credit; fully convertible currency is available for this purchase. An outline of applicable Terms and Conditions appears in Annex Three.

Instructions for Response:

Please indicate prices for all items you wish to offer by completing the table in Annex One. Your response should also include the following:

1. Payment terms offered, including currency of payment. For the purpose of price comparison, all offers will be converted to US dollars at the rate effective on the day indicated as the last day for receipt of quotations.
2. Availability:
   a. Items and quantities available for shipment to [country] by delivery date(s) indicated in the Schedule of Requirements (Annex One).
   b. Estimated dates for availability of remaining balance.
3. Information on manufacturer's standard packaging configuration:
   a. Number of units per package and per shipping box.
   b. Technical description of shipping box for each product, including gross weight and dimensions.
4. Copy of package inserts (as applicable) normally shipped with product and copy of customary product labeling.
5. Information on product approvals:
   a. Please indicate if the product has been prequalified by the World Health Organization or approved for use by any other international agencies, or licensed by the national control authority of other countries. Submit list.
6. Copy of product registration or licensing in country of manufacture (as applicable).
7. Copy of recent Certificate of Analysis pertaining to each product offered (as applicable).

8. Business information and customary financial data.
   a. Name and address of production facility.
   b. Type of organization.
   c. Affiliations, parent company, or subsidiary relationships.
   d. Number of years in business.
   e. Countries to which products are presently exported.
   f. Approximate annual sales in US dollars.
9. Sample of each product offered.

Offers shall be made in English and will be translated into [language] upon receipt in [country]. Alternately, prospective suppliers may provide translations with their offers.

Offers shall be valid for ninety (90) days from date of initial response.

Annex One [name of procuring entity]

Request for Quotation Number _____

SCHEDULE OF REQUIREMENTS

Product *Strength*	A *xx*	B *xx*	C *xx*	D *xx*
Quantity in Doses				
Date for Delivery				
No. of Shipments				
Shelf Life*				

*remaining on delivery date

PRICE OFFER

Product	A	B	C	D

Please enter prices in US dollars in appropriate boxes.

Period of Validity:

_____

Signature: _____

Date: _____

For: _____
[name of company]

Annex Two [name of procuring entity]

Sample Technical Specifications: Injectable Contraceptives (with visual inspection guidelines)

Notes (for submission of sample)

The sample injectable contraceptives submitted by the Bidder in response to this Invitation for Bids must be exactly the same[13] as would be supplied if a contract were awarded to the Bidder. The vial or ampoule containing the product need not have a printed logo; however, other information as stipulated under Clause 1.11 of this specification must be furnished. For sample submission only, this information (logo optional) may be printed on a sticker and affixed to the vials or ampoules containing the product.

1. Requirements

Injectable contraceptives in accordance with the following specifications:

- *Long-acting progestin in sterile aqueous suspension for intramuscular injection once every three (3) months.*
- *Each 1-ml vial or ampoule should contain a minimum of 1.1 ml of sterile aqueous suspension containing 150 mg/ml medroxyprogesterone acetate*.

1.1 Product and Brand Names

Product name: _____

Brand names: _____

1.2 Raw Materials

Injectable contraceptives offered under this purchase description shall be produced from validated raw materials obtained from a licensed manufacturer or its authorized distributor.

1.3 Primary Packaging Requirements

Injectable contraceptives offered under this purchase description shall be packaged in vials or ampoules that meet quality standards as specified in ISO 8362-1. Closures for injection vials shall meet quality standards as specified in ISO 8362-2.

1.4 Registration Requirements

Injectable contraceptives offered under this purchase description shall be currently registered in the country of destination and approved by _____ *(local regulatory authority).*

1.5 Certificate of Licensing Status

Injectable contraceptives offered under this purchase description shall be licensed for marketing by the drug regulatory authority of the country of origin. Prior to award of the

[13] For example, vial or ampoule must be same glass type, closure type, color, size, text, and identification markings; contents must have same ingredients, color, and weight; same inner box size, material, text, and identification markings.

Contract, the successful offerer(s) may be required to submit a "statement of licensing status of pharmaceutical product(s)" as provided under the World Health Organization (WHO) Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce.

1.6 No Objection Certificate

In the case of goods of foreign origin, injectable contraceptives offered under this purchase description shall have been awarded a No Objection Certificate by _____ *(local regulatory authority)* on behalf of any local manufacturer(s) of the importing country.

1.7 Compliance with Current Good Manufacturing Practices

The Supplier must be able to provide certification that the injectable contraceptives are manufactured according to WHO current good manufacturing practices (cGMP). Such certification can be found in the WHO Certification Scheme "Certificate of Pharmaceutical Product." Supplier also must be able to provide copies of its annual cGMP audit reports.

1.8 WHO Certification—Movement in International Commerce

The Supplier must be able to provide documentation indicating that the manufacturer of the product has received confirmation from the Ministry of Health of the country of manufacture that the pharmaceutical meets the requirements in the WHO Certification Scheme.

1.9 Appearance

Injectable contraceptives shall appear as an aqueous white suspension contained in 1-ml or 10-ml glass vials or 1-ml glass ampoules.

1.10 Filling Volume

Each 1-ml glass vial or ampoule shall contain a minimum of 1.1 ml of sterile aqueous suspension.

Each 10-ml glass vial shall contain a minimum of 10.5 ml of sterile aqueous suspension.

1.11 Identification Markings on Individual Vials or Ampoules

Each individual vial or ampoule shall have the following information:

- Product/brand name.
- Lot/batch number.
- Expiration date (month and year).
- Date of manufacture.
- Manufacturer's name and address.
- Presentation (e.g., *sterile aqueous suspension*).
- Formulation (amounts of active ingredients per vial or ampoule).
- Drug registration number (if applicable).
- Family planning logo (if applicable).

If space allows, the following information shall also appear on each individual vial or ampoule:

- Recommended storage conditions.
- Made in _____.

1.12 Workmanship

Products and packaging shall be free of defects that impair their serviceability, affect their durability, or detract from their appearance.

1.13 Lots Per Order

The Supplier shall fill the order using the fewest number of manufacturing lots possible.

1.14 Shelf Life

The shelf life of the product provided under this solicitation shall be at least *three (3) years* from the date of manufacture when stored under tropical conditions such as those prevailing in _____ *(recipient country name).* The Supplier shall be able to provide to the satisfaction of the registration/national quality control authorities the manufacturer's stability test data substantiating this *three (3)-year* shelf life at ambient temperatures at or greater than 32 degrees Celsius and at a relative humidity of 85% in the proposed vial or ampoule.

At the time of inspection or acceptance for delivery to the country of destination, no more than nine (9) months shall have expired since the date of manufacture shown on the batch release or Certificate of Analysis.

1.15 Test Data

Chemical, physical, and microbiological test data for raw materials, components in-process, and finished product testing must be on record for each lot shipped and must be available to Purchaser's representatives when requested.

2. Quality Assurance Provisions

2.1 Compliance

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

2.2 Documentation

2.2.1 The Supplier shall provide evidence[14] of the satisfaction of the technical specification requirements for which specific inspection or protocols have not been provided. Such evidence is contained in the "Manufacturer's Batch Certificate of a Pharmaceutical Product" under the WHO Certification Scheme.

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

[14] **Including quality control and manufacturing records, in-process control records, and final product Certificate of Analysis.**

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

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

2.3 Inspection by the Purchaser

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

The Purchaser may have some or all of the tests specified in the Contract performed by a laboratory suitably equipped and qualified to conduct quality assurance tests on pharmaceutical products according to _____ Pharmacopoeia.

2.4 Sampling Procedures

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

Where an inspection lot is smaller than 10,001 units, it will be deemed to be 10,001 for determination of sample sizes.

The normal, tightened, and reduced inspection provisions of ISO 2859 (Inspection by Attributes) may be used for visual inspection. Sampling for analytical testing shall be done in accordance with pharmacopoeial requirements.

All sampled boxes and shipping cartons shall be so marked and shall include the date and initials of the sampler.

2.5 Sample Retention

The Supplier shall retain a sample of ten (10) vials or ampoules, or the equivalent required to perform three (3) complete chemical assays, from each lot shipped, for a period of one (1) year after the printed expiration date.

3. Packing

3.1 Inner Boxes

3.1.1 *One hundred (100) individual glass vials or ampoules* will be contained in sturdy white cardboard boxes outfitted with individual segments for protecting and separating each vial or ampoule.

Inner boxes shall be made of sturdy white cardboard of a size sufficient to contain the specified number of vials or ampoules. The overall dimensions should be such that the product does not get damaged during transportation and storage.

3.1.2 For inner boxes, the Supplier shall fill in the blanks provided below:

Each inner box will contain *one hundred (100) units*. The overall dimension of a box will be _____ cm x _____ cm x _____ cm.

3.2 Exterior Shipping Cartons

3.2.1 *Product and printed materials, packaged and packed as specified above, shall be contained in triple-wall corrugated fiberboard cartons made from weather-resistant fiberboard with a bursting test strength of not less than 1,900 kPa. The carton flaps shall be secured with water-resistant adhesive applied to not less than 75% of the area of contact between the flaps or with 75 mm-wide water-resistant tape applied to the full length of the center seams and extending over the ends not less than 75 mm. Plastic strapping shall be placed around the carton, with a minimum of two crossing bands. Cartons exceeding 760 mm (30 inches) in length shall have additional bands placed around the carton.*

3.2.2 Additional cushioning shall be provided as needed to protect the vials or ampoules from breakage during transit and handling.

3.2.3 The Supplier shall fill in the following blanks:

The exterior shipping carton will contain _____ inner boxes. The overall dimensions of a carton will be _____ cm x _____ cm x _____ cm, and the gross weight of one shipping carton will be _____ kg.

A standard 6.096 meter (20-foot) container will accommodate _____ exterior shipping cartons.

3.3 Markings

3.3.1 Inner Boxes

The inner boxes shall be marked with the following information in a clearly legible manner which is acceptable to the Purchaser[15]:

- Product/brand name.
- Lot/batch number.
- Expiration date (month and year).
- Date of manufacture.
- Manufacturer's name and address.
- Contents and quantity.
- Drug registration number (if applicable).
- Instructions for storage and handing.
- Formulation and presentation.

[15] **The smallest type shall be no less than 1 mm high, unless otherwise specified by the commercial laws of the country of importation.**

3.3.2 Exterior Shipping Cartons

The following information shall be stenciled or labeled on the exterior shipping cartons on two opposing sides in bold letters at least _____ mm high with waterproof ink in a clearly legible manner that is acceptable to the Purchaser.[16]

Regulatory information (on two opposing sides of carton)

- Product/brand name.
- Lot/batch number.
- Expiration date (month and year).
- Date of manufacture.
- Manufacturer's name and address.
- Contents and quantity.
- Drug registration numbers (if applicable).
- Instructions and symbols for storage and handling, such as KEEP DRY or DO NOT FREEZE.

Customs and shipping information (on two opposing sides of carton)

- Made in _____.
- Supplier's name and address (if different from manufacturer).
- Consignee's address in full.
- Gross weight of each carton (in kg).
- Port of entry.
- Contract number.
- Quantity of goods.
- Carton _____ of _____.

3.4 Printed Materials—Product Information Sheets

Twenty (20) patient information sheets and one (1) prescribing information sheet, printed in English and in _____, shall be included in each intermediate container.

Inspection Sampling and Testing—Injectable Contraceptives

Prior to shipment, the Purchaser or its appointed representative has the right to sample and inspect each consignment of injectable contraceptives at the factory or Supplier's warehouse in accordance with ISO 2859 Inspection by Attributes (or WHO specifications) and Technical Specification _____ of this Contract.

1.1 Packaging, Packing, and Markings

a. One hundred percent (100%) of the exterior shipping cartons will be examined for:

- General physical characteristics and condition.
- Markings per Technical Specification _____.

b. *A representative sample of the inner boxes and individual vials or ampoules will be drawn from the exterior shipping cartons at General Inspection Level II, or, at the discretion of the Purchaser, General Inspection Level III, Single Sampling Plan for Normal Inspection.*

[16] **The smallest type shall be no less than 10 mm high, unless otherwise specified by the commercial laws of the country of importation.**

The sample will be examined for:

- General physical characteristics per Technical Specification _____, Section _____.
- Markings per Technical Specification _____, Section _____.

c. Inspection criteria and classification of defects shall follow the inspection guidelines outlined in Section 1.4 below. For critical defects, the acceptable quality limit (AQL) shall be 0%; for major defects, the AQL shall be 1%; for minor defects, the AQL shall be 4%.

1.2 Injectable

At the discretion of the Purchaser, part of the selected sample may be sent to a qualified independent laboratory for physical, chemical, or microbiological testing as follows.

Pharmacopoeial tests:

- Active ingredient(s) identification and assay.
- Appearance (color, turbidity, visible particles).
- Filling volume.
- pH.
- Preservative identification.
- Pyrogens.
- Sterility.

Nonpharmacopoeial tests:

- Package seal integrity test.
- Particle size (for suspensions only).

A Certificate of Analysis for production lot(s) represented by test samples shall be made available to the inspector and/or Purchaser upon request. The certificate shall state all tests performed, their specifications, and actual test results obtained. All pharmacopoeial tests results shall meet applicable pharmacopoeial limits.

1.3 Resolution of Defects

a. Packaging, Packing, and Markings

Defects in exterior shipping carton markings must be corrected by the Supplier prior to shipment.

All goods from corresponding production lots with inspection lot defect in excess of the AQLs listed in Section 1.4 of this specification must be corrected and reinspected at Supplier's expense or rejected.

b. Injectable

Any deviation from manufacturer's Certificate of Analysis, product specifications, or relevant pharmacopoeial limits shall result in rejection of goods from the entire production lot.

1.4 Visual Inspection Review Guidelines for Injectable Contraceptives

Injectable contraceptives are available in several formulations, including oil-based and aqueous suspension and dosage forms. Contraceptive protection per dose ranges from 1 month to 3 months depending on the product. Injectables are available in prefilled syringes, but are most commonly provided in single- or multidose vials or ampoules with disposable syringes. Shelf life for injectable contraceptives ranges from 2 to 5 years depending on the

formulation. Recommended storage temperature generally is 15 to 30 degrees Celsius. Storage temperature is critical to product stability; oil-based solutions become rancid at elevated temperatures. Manufacturers' recommended storage conditions should be followed.

The labeling criteria listed below are comprehensive and useful not just in identifying the product, but in managing it successfully within the logistics system. However, not all contraceptives are procured with such extensive labeling specifications. If any of the labeling criteria listed below are not applicable, mark the appropriate box in the "n/a" (not applicable) column. Product procurement specifications should be consulted prior to finalizing the inspection criteria.

Product labeling criteria—injectable contraceptives

Date: _____	Receipt Report Number: _____
Product: _____	Lot Number: _____
Brand Name: _____	Manufacturer: _____
Expiration Date: _____	Date of Manufacture: _____
Inspection of Lot Size: _____	Sample Size: _____
Warehouse Location:	Second Sample Size:

Visual Inspection Criteria	Meets Criteria Yes	No	n/a	Defect Classification
Shipping Cartons Examine 100 percent (100%) of the shipping cartons against the shipping documents				
Carton Labeling:				
Product/brand name	☐	☐	☐	Major
Lot/batch number	☐	☐	☐	Major
Expiration date	☐	☐	☐	Major
Manufacturer's name and address	☐	☐	☐	Minor
Date of manufacture	☐	☐	☐	Minor
Contents and quantity	☐	☐	☐	Minor
Drug registration number	☐	☐	☐	Minor
Storage instructions	☐	☐	☐	Minor
Carton Condition/Content:				
Carton in good condition, undamaged	☐	☐	☐	Major
All inner boxes present, none missing	☐	☐	☐	Major
Proper flap/closure	☐	☐	☐	Minor
Inner Boxes				
Inner Box Labeling:				
Product/brand name	☐	☐	☐	Critical
Lot/batch number	☐	☐	☐	Critical
Expiration date	☐	☐	☐	Critical
Manufacturer's name and address	☐	☐	☐	Minor
Date of manufacture	☐	☐	☐	Minor
Contents and quantity	☐	☐	☐	Minor
Drug registration number	☐	☐	☐	Minor
Storage instructions	☐	☐	☐	Minor
Inner Box Condition/Content:				
Inner box in good condition (undamaged, unopened)	☐	☐	☐	Major
All unit packages present, none missing	☐	☐	☐	Major

Visual Inspection Criteria	Meets Criteria Yes	No	n/a	Defect Classification
Inner box contains no foreign matter	☐	☐	☐	Minor
Unit Packages				
Unit Package Labeling:				
Product/brand name	☐	☐	☐	Critical
Lot/batch number	☐	☐	☐	Critical
Expiration date	☐	☐	☐	Critical
Manufacturer's name and address	☐	☐	☐	Critical
Date of manufacture	☐	☐	☐	Critical
Product use instructions	☐	☐	☐	Critical
Dosage	☐	☐	☐	Critical
Contents and quantity of doses	☐	☐	☐	Major
Drug registration number	☐	☐	☐	Major
Storage instructions	☐	☐	☐	Minor
Unit Package Condition/Content:				
Glass vial or ampoule in good condition (undamaged, unopened)	☐	☐	☐	Critical
Vial or ampoule free of foreign matter	☐	☐	☐	Critical
Vial or ampoule free of leakage	☐	☐	☐	Critical
Vial or ampoule free of solid material or caking	☐	☐	☐	Critical
Correct color	☐	☐	☐	Critical
Sufficient number of syringes for contraceptive doses	☐	☐	☐	Critical
Good vial seal, no breaks	☐	☐	☐	Critical

Definitions: Acceptable Quality Limits	
Critical defect	A defect which, according to experience and professional criteria, makes the product dangerous or not viable for its intended use.
Major defect	A defect which is unlikely to reduce usability and may make product use more difficult, but does not have the safety and efficacy risk associated with a critical defect.
Minor defect	A defect that is unlikely to affect usability of the product, but represents a departure from the specifications.
When these guidelines are used to ensure compliance with procurement specifications, the following acceptable quality limits (AQLs) shall apply: for critical defects, AQL 0%; for major defects, AQL 1%; for minor defects, AQL 4%.	

Annex Three [name of procuring entity]

Request for Quotation Number _____

TERMS AND CONDITIONS

Shipping Terms:	CIP [name of city, country, and port of entry]
Transport Mode:	Ocean
Trans-shipment:	Not allowed
Partial Shipments:	By agreement
Final Destination:	[name of city and country]
Payment Terms:	Negotiable, or by irrevocable letter of credit

Inspection and Testing: Preshipment compliance program

[Name of procuring entity] reserves the right for a designated representative to inspect, sample, and test, or cause to be tested, each lot of goods proposed for shipment to [country] for conformance with contract requirements BEFORE said shipment leaves the manufacturing facility.

Documents: (a) Quality documents for each shipment:

1. Lot release letter from the government regulatory authority in the country of manufacture.
2. Evidence of product and facility registration/licensing in the country of manufacture.
3. Certificate of Analysis for lot(s) being supplied.

The above documents shall be provided three (3) weeks prior to scheduled shipment.

(b) Commercial documents for each shipment:

1. Commercial invoice, bill of lading, packing list, Certificate of Origin, insurance certificate.

Packing: Goods must be packed in accordance with the procurement requirements in Annex Two.

Markings: The exteriors of all shipping cartons or containers must be marked in accordance with the procurement requirements in Annex Two. Other pertinent shipping label information will be provided prior to shipment.

Notification: The Supplier will keep [procuring entity] informed of any circumstances that might affect the delivery schedule.

Supplier will confirm shipping date to [procuring entity] three (3) weeks prior to dispatch and provide details as early as known.

Warranty: The Supplier shall warrant that the goods supplied to the [procuring country/ministry/agency] comply with all provisions of the procurement requirements and related documents.

Contract Award:

Contracts will be awarded on the basis of the most advantageous and lowest evaluated cost offer that conforms to this Request for Quotation. In addition to price, criteria for evaluating the offers will include _____.

The [procuring entity] reserves the right to award separate contracts for different portions of the goods covered by the Request for Quotation, or to combine different items into one contract.

A copy of the Purchaser's draft contract is available upon request.

k. Alternate Request for Quotation (Simplified)

Example Request for Quotation (simplified)

To: Date:

From:

[Name of procuring entity] requests your quotation for the supply of _____. This [product] will be distributed as part of the _____ program sponsored by _____. Below is information regarding product specifications, quantity requirements, and delivery schedules, along with instructions for submitting offers. A draft of the contractual terms and conditions under which these goods are expected to be supplied is enclosed for your reference. Please address any questions you may have in writing to _____. General clarifications and supplemental information provided to you as a result of your inquiry also will be provided to the other invited participants in this Request for Quotation.

A. Requirements

a. Specifications:
b. Licensing:
c. Delivery date required:
d. Shipping terms:
e. Payment terms:
f. Shipment via:
g. Documents to be provided with each shipment:

B. Rules to be followed in preparing your quotation

a. Prices must be itemized as follows:
   i. Goods
   ii. Freight
   iii. Insurance
   iv. Handling fees
   v. Export packing
   vi. Inspection
   vii. Inland transportation
   viii. Other
b. Offers must be valid for ninety (90) days from the date of the quotation.
c. Offers must be signed by an authorized representative of the offering firm in order to be considered valid.
d. Five (5) samples with package insert must accompany each offer.
e. Offers must be presented to this office on or before _____; submissions via fax or email are acceptable provided they are followed within ten (10) days by a signed original.

C. If you are not currently registered with [procuring entity/government] as a prequalified supplier, you must submit a completed and signed prequalification questionnaire with your quotation.

a. Questionnaire is available upon request from _____.
b. Questionnaire is attached _____.

The [procuring entity] looks forward to receiving your offer.

Sincerely, *[lead purchasing officer]*

3. Websites

a. World Bank Sites

***Standard Bidding Document: Procurement of Health Sector Goods* (revised August 2008)**

This standard bidding document is intended for purchasers to use in soliciting bids for supply of pharmaceuticals, vaccines, condoms, nutritional supplements, and oral and injectable hormonal forms of contraception through international competitive bidding. It includes clauses needed to ensure product quality and safety, and addresses requirements for licensing by the NRA.

http://web.worldbank.org/WBSITE/EXTERNAL/PROJECTS/PROCUREMENT/0,,contentMDK:21890171~menuPK:84284~pagePK:84269~piPK:60001558~theSitePK:84266~isCURL:Y,00.html

Technical Note

This technical note was appended to an earlier version of the health-sector bidding document. It was designed to help World Bank personnel and borrowers understand some of the unique aspects of purchasing health-sector goods. It is still useful, and still available on the World Bank's website at http://siteresources.worldbank.org/PROCUREMENT/Resources/health-tn-ev2.doc.

***Standard Prequalification Document: Procurement of Health Sector Goods* (Trial Edition, 2002)**

The standard prequalification document is used following the advertisement of a general procurement notice. The template outlines an invitation for prequalification for a specific procurement notice. It is intended primarily for use in prequalifying applicants that express an interest in bidding on the supply of health-sector goods.

http://web.worldbank.org/WBSITE/EXTERNAL/PROJECTS/PROCUREMENT/0,,contentMDK:50004187~menuPK:84284~pagePK:84269~piPK:60001558~theSitePK:84266,00.html

b. World Health Organization Sites

***Practical Guidelines on Pharmaceutical Procurement for Countries with Small Procurement Agencies* (WHO Regional Office for the Western Pacific, 2002)**
This moderate-size guideline melds good pharmaceutical procurement practice with procedures for good public-sector procurement and offers detailed guidance on prequalification and restricted bidding.

http://www.wpro.who.int/NR/rdonlyres/7D1B522D-DEB1-48CB-88A7-68DEB599CCE1/0/PharmaProcurementGuide.pdf

***The Male Latex Condom: Specification and Guidelines for Condom Procurement* (WHO/UNFPA/Joint United Nations Programme on HIV/AIDS [UNAIDS], 2003)**
This document developed by WHO is designed to provide a set of purchase specifications and procurement guidelines that ensure the highest level of QA for condoms consistent with high-volume purchases, the needs of different populations, harsh environmental conditions, and the probability of less-than-ideal storage conditions. It recommends the prequalification of primary manufacturers and lot-by-lot compliance testing prior to shipping condoms from the country of manufacture. The document also provides a list of manufacturers and testing laboratories *for informational purposes only*. Appearance on this list does not imply endorsement by WHO, UNFPA, or UNAIDS.

http://www.who.int/reproductivehealth/publications/family_planning/9241591277/en/

Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce: model Certificate of Pharmaceutical Product, model Batch Certificate of a Pharmaceutical Product
A format on a certification scheme is available in *Operational Guide for National Tuberculosis Control Programs* (Annexes 2 and 3).

http://whqlibdoc.who.int/hq/2002/WHO_CDS_TB_2002.308.pdf

Guidelines on the Implementation of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce
The WHO website provides guidelines on the WHO Certification Scheme. The guidelines cover provisions and objectives, eligibility for participation, requesting a certificate, issuing a certificate, and notifying and investigating a quality defect.

http://www.who.int/medicines/areas/quality_safety/regulation_legislation/certification/guidelines/en/

J. Learning Evaluation

1. What are the headings of the key sections that should be included in bidding documents?
2. Why are General Conditions of Contract included in bidding documents?
3. Why are Special Conditions of Contract included in bidding documents?
4. What is the relationship between the General Conditions of Contract and Special Conditions of Contract?
5. What challenge does the purchaser face in preparing good public-sector bidding documents?
6. What is the first step a purchaser should take in preparing draft bidding documents?
7. In preparing the Special Conditions of Contract, what are some key areas that will require careful consideration and wording?
8. What is the benefit to the purchaser of including a clause in the Special Conditions of Contract that allows the purchaser the right to vary quantities at the time of award?
9. What are the purchaser's responsibilities following a pre-bid conference?
10. What are the basic rules for receiving and managing bids from suppliers?

Learning Evaluation Answers

1. The key headings of the bidding documents are:

    a. General Instructions to Bidders.

    b. Special Instructions to Bidders.

    c. Eligible/Ineligible Countries.

    d. General Conditions of Contract.

    e. Special Conditions of Contract.

    f. Technical Specifications.

    g. Schedule of Requirements.

    h. Evaluation Criteria.

    i. Qualification Criteria.

    j. Bid and Contract Forms.

    See Section D.2.

2. The General Conditions of Contract are included in the bidding documents to provide the clauses that will apply to the future contract. The clauses cover ordinary contract issues such as delivery, payments, warranty, termination, force majeure, governing language, and notices. See Section D.2.d.

3. The Special Conditions of Contract are included in the bidding documents to supplement and/or modify the General Conditions of Contract. They address unique requirements such as regulatory compliance issues and preshipment inspection and testing. See Section D.2.e.

4. The Special Conditions of Contract are numbered to reference the corresponding section in the General Conditions of Contract. See Section D.1.

5. The challenge faced when preparing good public-sector bidding documents is that changes in one part of the document often require changes in another, and the basic principles in the standard mandatory clauses must not be violated. See Section E.

6. The first step a purchaser should take when drafting bidding documents is to become familiar with the bidding documents and make a list of the information needed to complete them. See Section E.1.

7. The key areas that require careful consideration and wording in the Special Conditions of Contract are certification of goods, inspections and tests, packing and markings, payment conditions and method of payment, delivery, and warranty. See Section E.3.p.

8. The benefit to the purchaser to include a clause allowing the right to vary quantities at the time of award provides an option (other than canceling the bidding) if prices offered exceed the available budget. On the other hand, if prices are lower than expected, the purchase of additional product might be attractive. See Section E.3.l.

9. The purchaser's responsibilities following a pre-bid conference are to provide a copy of the minutes and any deferred answer in sufficient time, before the submission deadline. See Section F.3.e.

10. The basic rules for receiving and managing bids from suppliers are:
    - Bids must be held unopened until the stated day and time of bid opening.
    - Bid envelopes should be stamped with the date and time they are received.
    - Except for questions and answers in writing to/from the procuring entity, no one associated with the procurement is permitted to communicate with bidders regarding the bid from the time the advertisement appears until after an award has been made. See Section F.5.

K. Performance Indicators

Performance indicators measure and evaluate success against a specific goal. The process begins by selecting performance indicators that are relevant for the procurement environment. This is followed by identifying and collecting appropriate data for each performance indicator to establish a baseline on the level of performance in the country. After training and corrective actions have been implemented, the same performance indicators are evaluated to determine the revised level of performance. Further information on conducting an assessment can be found in the Procurement Assessment Guide.

The following performance indicators can be used for monitoring and evaluating key aspects of this module:

1. Percentage of the following components of standard public-sector bidding documents that appear in the bids reviewed for the RH commodities selected:
   - general instructions to bidders
   - special instructions to bidders
   - eligible/ineligible countries
   - general conditions of contract
   - technical specifications
   - schedule of requirements
   - evaluation criteria
   - qualification criteria
   - bid and contract forms
   - instructions regarding shipping
2. Percentage of competitively bid contracts that are publicly advertised.
3. All bids received prior to the deadline are stored in a secure location.
4. Public bid openings are conducted.
5. The procurement unit has a system to maintain accurate records of all communications with bidders both before and after bid submission.

L. Glossary and Acronyms

Agent	A supply term for an independent contractor authorized by a manufacturer to promote and sell the manufacturer's products within a designated geographic area. Often, an agent will contract to represent several manufacturers of noncompeting products.
AIDS	Acquired Immunodeficiency Syndrome.
AQL	Acceptable quality limit: The lowest allowable limit of quality in a lot.
Batch Certificate of a Pharmaceutical Product	A document issued for each batch by the manufacturer certifying the quality and expiry date of a specific batch of a product that has already been licensed in the importing country.
Beneficiary	A legal term used in banking to describe the party entitled to collect funds guaranteed by a commercial letter of credit upon presentation of stipulated documents (usually shipping and quality assurance documents). Also known as the seller.
Bid	A procurement term describing a written offer for a quantity of goods, works, or services at a stated price based on a technical specification and specific terms and conditions. Bids are submitted to an intending purchaser by an intending seller in response to an Invitation for Bids.
Bid Data Sheet	Term for the World Bank bidding document that modifies the Instructions to Bidders document by providing information specific to the bid.
Bidder	An intending seller or supplier that submits a bid offering goods or services in response to an invitation or request for bids and offers.
Bidding documents	The written description and set of terms and conditions of an intended purchase that is circulated by the intending buyer to prospective sellers.

Bid security	A financial instrument used to guarantee compensation to the prospective buyer for inconvenience and expense if a winning bidder rescinds its offer after the bid is closed and an award has been made to the bidder. Each bidder provides an amount stated in the bidding documents with its bid submission.
Bill of lading	A shipping document issued by a carrier (usually an ocean shipping line) to a shipper that provides a written receipt for the goods, describes the conditions by which transport is made, and includes a written commitment to deliver goods at a stated destination to the lawful holder of the bill of lading.
Brand/Brand name	The registered trademark name given to a specific product by its manufacturer.
Certificate of Analysis	A document certifying quality and composition of goods.
Certificate of Pharmaceutical Product	A certificate establishing the status of the pharmaceutical product and of the applicant for the certificate in the exporting country. It is for a single product only, since manufacturing arrangements and approved information for different dosage forms and strengths can vary.
cGMP(s)	Current good manufacturing practice(s): Manufacturers must employ technologies and systems which are up to date to the performance standards for pharmaceutical and medical device manufacturers established by the World Health Organization and many national governments. Includes criteria for personnel, facilities, equipment, materials, manufacturing operations, labeling, packaging, quality control, and in most cases, stability testing.
CIP	Carriage (freight) and insurance paid to: Costs paid to the named destination by the seller. Title and risk pass to buyer when delivered to carrier.
Commercial invoice	Document required by customs to determine the true value of imported goods for assessment of duties and taxes.

Commodity	Any piece of tangible property, supplies, or equipment that is the subject of a procurement activity.
Compliance testing	A methodology of prescribed inspection and testing procedures applied to a product to ensure the product meets its defined specifications and/or performance requirements.
Component	An important function or process that occurs within an element of the reproductive health supply process. Each module of the *Toolkit* focuses on one element.
Contract	An agreement entered into by two parties for the execution of a certain activity (e.g., sale and purchase, construction, service provision, etc.).
Criteria	Specific points, standards, qualities, and/or requirements against which something is judged.
Debarred	Denied opportunity to compete for contracts of a purchasing authority.
Documentary evidence	Being, consisting of, or contained exclusively in documents.
Domestic preference	A term used in World Bank procurement documents to describe a competitive advantage, expressed in a percentage, that is sometimes given to local manufacturers of goods competing for contracts against international sources.
Drug regulatory authority	Same as national regulatory authority: An independent government entity responsible for establishing procedures to ensure that medicines intended for use in the country are safe, potent, and effective.
Efficacy	The capacity of a drug to produce scientifically proven therapeutic effects.
Element	One of the ten key operational, broad-based activities in the reproductive health supply process.

Eligibility (criteria)	Not excluded from competing for contracts in general by reason of nationality, debarment, lack of regulatory approval, etc.
Entity	A business and legal term to describe something that exists and functions as a separate and distinct body (e.g., a corporation, Ministry of Health, or committee).
e-Procurement	The automation of any part of the procurement process with electronic tools, ranging from a system that is fully integrated with purchasers' systems (e.g., linked with the warehouse management system), to partial automation of an organization's processes, to simply using a supplier's online tools.
Evaluated cost	An offered price adjusted for corrections, discounts, domestic preference, and usage factors.
Evaluation criteria	Basis for judgment (announced in bidding documents) that will be used to select the winning bidder.
Expiration (Expiry) date	The date beyond which the manufacturer will not guarantee the product.
Fast-track licensing	Regulatory licensing based on confidence in the quality of a product as evidenced by similar licensing in countries with stringent, highly respected regulatory authorities.
Force majeure	Unforeseen circumstances (e.g., natural disasters, other "Acts of God," or war) which excuse a party from fulfillment of a contract.
Formulation	The amounts of active ingredients per tablet.
Funder	Organization (or person) providing funds for a specific project, program, or purpose.
General Conditions of Contract	Mandatory contract wording for issues such as payments, obligations, risks, rights, and performance.
HIV	Human Immunodeficiency Virus.

INCOTERMS	Rules for interpretation of the most commonly used terms in foreign trade to describe how goods will be shipped, who is responsible for them at each stage of the process, and who pays which costs. Published by the International Chamber of Commerce.
Injectable	Injectable contraceptive.
International nonproprietary name	A name that facilitates the identification of a pharmaceutical substance or active pharmaceutical ingredient. Each international nonproprietary name is a unique name that is globally recognized and is public property (also known as a generic name).
Invitation for Bids	An invitation to manufacturers or contractors, through a bidding process, to submit a proposal on a specific product or service to be furnished.
ISO	International Organization for Standardization: A nongovernmental organization that develops and publishes international standards. It is a network of the national standards institutes of 162 countries.
ITB	Instructions to Bidders.
L/C	Letter of credit: An arrangement by banks for settling commercial transactions; specifically, a written promise by a bank given to the seller in accordance with instructions (backed by a cash deposit) of the buyer to pay up to a given sum of money within a prescribed time limit when and if the seller presents specified documents that give evidence of its performance.
Lot (Batch)	In manufacturing, a single, uniform, and homogeneous quantity produced from one compounding formulation, in one manufacturing and production operation, and that has received entirely the same processing treatment.
Lot (Batch) number	A series of numbers or letters, or both, established to record production and control of a product. Unless otherwise specified, the lot number is the series of numbers or letters that identifies a single, uniform, and homogeneous

	quantity produced from one compounding formulation, in one manufacturing and production operation, and that has received entirely the same processing treatment. Lot size varies by product, product type, dosage form, and manufacturing process.
Lot-by-lot	Applicable to each manufacturing lot (batch).
Major (Material) Deviation	Used in evaluating bids to describe a significant and unacceptable difference from the requirements stated in the bidding documents. More precisely, a material deviation is one that affects, in any way, the price, quantity, quality, or delivery of the goods as required in the bidding documents, or limits in any way the responsibilities, duties, or liabilities of the bidder or any rights of the purchaser. See Module 7 for more information.
Manufacturer's (Bidder's) representative	A direct employee of a manufacturer with responsibility to promote the use of, provide information on, and sell the manufacturer's products. In some cases, the representative also facilitates importation. Sometimes the term "agent" is used to convey the same relationship.
Marks, markings	An application of numbers, letters, labels, tabs, symbols, or colors for handling or identification during shipment and storage.
N/A (n/a)	Not applicable.
Negotiated procurement	A competitive procurement method in which proposals are requested from suppliers and the purchaser can discuss the supplier proposals to determine the best value.
No Objection Certificate	Issued by a manufacturer or a government when goods to be imported into a country are already manufactured in that country. States that there is no objection to the goods being imported.

NRA	National regulatory authority (same as drug regulatory authority): An independent government entity responsible for establishing procedures to ensure that medicines intended for use in the country are safe, potent, and effective.
Null and void	Cancellation or lapse of an agreement (contract) with no legal effect.
Offer	Used interchangeably with "bid," "tender," and "proposal."
Packaging	The primary wrapping and marking of a product.
Packing	The assembling of a packaged product into multiple units. Prepared for shipment in appropriate cartons or crates with all necessary blocking, bracing, cushioning, weatherproofing, reinforcement, and markings.
Performance indicator	Measures and evaluates success against a specific goal.
Performance security	A procurement term describing the financial instrument used to guarantee compensation to the buyer for inconvenience and expense if the seller does not perform (i.e., does not produce and ship the contracted goods or provide the contracted services within the stated period). The seller puts up its own funds, often through a bank or insurance company, to be held in reserve until the contract terms have been met.
Pharmaceutical Inspection Convention	One of two international instruments (Pharmaceutical Inspection Co-operation Scheme is the other) between countries and pharmaceutical inspection authorities dedicated to standardizing and ensuring current good manufacturing practices and inspections. Currently, it has 31 member countries, with the European Medicines Agency, the United Nations Population Fund, and the World Health Organization as partners/observers.
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Phase	A natural division of the ten elements of the supply process into three sequential parts: program planning, procurement process, and contract performance.
Prequalification (of manufacturer/ supplier/bidder)	A process of preapproving suppliers for participation in bids based on a judgment of reliability, technical competence, and financial stability.
Prequalification (of product)	A process of predetermining that a specific product (usually a pharmaceutical, device, or vaccine) of a specific manufacturer meets stated requirements.
Preshipment compliance	Process by which the purchaser confirms the acceptability for shipment of the supplier's commodity prior to shipment. There are three basic levels of preshipment compliance a purchaser can institute, ranging from document review to visual inspection up to full laboratory or physical testing of the commodity.
Preshipment inspection	An inspection of manufactured goods ready for shipment undertaken by an internationally recognized inspection agency (such as Societe Generale de Surveillance).
Procurement method	Process a purchaser uses to reach an agreement with a seller.
Procurement option	Approach to procurement: Direct or indirect, and several subdivisions of each are differentiated by who contracts with the original manufacturer (or its representative).
Procurement requirements	A complete description of the product to be purchased, including technical attributes (especially manufacturing and quality assurance norms), program specifications (including packaging and packing), shipping terms, payment

	terms, port of delivery, delivery date, quantity, documentation, and any other relevant detail of the expected purchase.
Procurement requisition	A document describing what is to be purchased and giving authority to do so.
Procurement unit	Individuals organized around procurement duties within a larger entity.
Product neutral	Specifications that use generic terms, relative characteristics, and performance requirements rather than brand names and superficial descriptions.
Purchase order	A commercial document issued by a buyer (purchaser) to a seller indicating the type, quantities, and agreed prices for products or services the seller will provide to the buyer. Purchase orders usually specify additional conditions such as terms of payment, INCOTERMS for liability and freight responsibility, any inspection or testing procedures that may be required, and required delivery date.
QA	Quality assurance. For more information, see Supplementary Topics, Section H: Product Quality Assurance.
Qualification criteria	An attribute that must be met or complied with that makes a competing firm fit to perform a specific contract.
Registration	A term used in regulating medicines, pharmaceuticals, and vaccines; exact usage varies from country to country. It is often synonymous with licensing, but it can mean simply that the particulars about a shipment are recorded as it enters a country.
Request for Quotation	A procurement method without sealed bidding or formal bidding procedures in which potential suppliers are contacted and asked to provide a price for specified goods.
RH	Reproductive health: A state of complete physical, mental, and social well-being—not merely the absence of disease or infirmity—in all

	matters relating to the functions and processes of the reproductive system. Reproductive health implies that people are able to have a satisfying and safe sex life and that they have the capability to reproduce and the freedom to decide if, when, and how often to do so; implicit in this last condition is the right of men and women to be informed and to have access to safe, effective, affordable, and acceptable methods of family planning of their choice, as well as other methods of their choice, for regulation of fertility.
Schedule of Requirements	Part of bidding documents that describes the quantity of goods and expected delivery time.
Sealed bids	A procurement process in which formal bids are submitted in sealed envelopes and held unopened until an appointed date and time, then opened and read in public with bidders in attendance.
Shipping term	Generally an INCOTERM.
Special Conditions of Contract	Modifies or adds to General Conditions of Contract to suit specific goods and situations.
Specification	A definitive description of the commodity to be procured.
Substantially responsive	A bid that contains no material deviations from or reservations to the terms, conditions, and specifications in the bidding documents.
Supplier	The party that transfers goods out of its own control to a named recipient.
Supply	Goods and services of a specific kind that are provided to businesses, public agencies, or directly to consumers.
Turnover	The amount of business transacted during a given period of time; for example, annual sales value.
UNAIDS	Joint United Nations Programme on HIV/AIDS: Brings together the efforts and resources of ten United Nations system organizations in the AIDS response to help the world prevent new HIV infections, care for people living with HIV, and mitigate the impact of the epidemic.

UNFPA	United Nations Population Fund: A semiautonomous United Nations agency working to ensure universal access to reproductive health, including family planning and sexual health, to all couples and individuals. Operates a global procurement service for public-sector purchasers of contraceptives and related products.
United Nations	An international organization founded in 1945 after the Second World War by 51 countries committed to maintaining international peace and security; developing friendly relations among nations; and promoting social progress, better living standards, and human rights.
Value added tax	A tax levied by governments on values added resulting from an exchange of property; for example, from wholesale value to retail value. Generally paid by the seller (but passed along to the customer via sale price).
Visual inspection	A comparison of a product to written specifications (e.g., packaging, labeling, and marking instructions) that is performed without the aid of test instruments.
Warranty	A written guarantee given to the purchaser of health-sector goods by the manufacturer or dealer, usually specifying that the manufacturer will replace poor-quality goods free of charge for a stated period of time.
WHO	World Health Organization: The directing and coordinating authority for health within the United Nations system.
WHO prequalification	Included on the WHO list of prequalified medicines. WHO assesses quality, efficacy, and safety of specific medicines from specific manufacturers and accepts or rejects them for inclusion on its list. For more information, see Supplementary Topics, Section E: Prequalification.
World Bank	The World Bank Group offers loans, advice, and an array of customized resources to more than 100 developing countries and countries in transition.