2 Specifications

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

This module covers Element 2 of the reproductive health (RH) supply process. It describes the considerations and processes necessary to develop technical specifications, which will help ensure delivery of a high-quality product that best meets the needs of the end user. Specification development is the second step in the program planning phase, which begins with defining requirements and proceeds with the selection of a procurement method and budgeting, after specification development is complete.

Purchasers of RH commodities are uniquely positioned to ensure the quality of products they purchase. The primary tool they use to do this is the technical specification. Well-written and complete specifications help ensure that purchased products are made with high-quality raw ingredients, in current good manufacturing practices (cGMP)-certified facilities, tested according to international standards, packaged in compliance with national requirements, stored under conditions that do not compromise their quality, and delivered to end users in good condition.

Specifications can be used to define a variety of areas, such as product information (quantity, size, color, and registration), manufacturing requirements (standards for raw materials and cGMP certification), testing requirements, and packaging and shipping requirements—all details that when taken as a whole, ensure product quality and acceptability to the end user.

While the focus of this module is on specifications, it is important to note the role that standards can play in specification development. Standards for products are traditionally developed and published by international and national regulatory authorities or standards bodies to establish the minimum level of performance and safety requirements for the product. Standards also generally specify methods of use when carrying out basic tests for quality verification.

The purchaser can incorporate a standard into a specification by reference to establish the minimum level of performance and safety required; however, the purchaser can also demand a higher level of product quality by including more detailed quality assurance (QA) requirements in the specification.

B. Learning Objectives

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

- Describe how specifications support the QA process.
- Cite methods for developing specifications.
- Develop the format and critical content of specifications.
- Locate available resources for RH commodity specifications.

C. Components, Considerations, and Challenges

1. Components

Each element of RH supply is made up of several components. Most components involve activities to be carried out by RH purchasers; others are dependent on activities performed by others.

The main requirements of RH purchasers at Element 2 are:

- Understanding of international and national quality standards for each RH commodity, including international testing requirements.
- Knowledge concerning national registration status, including expiry dates of current registered products and new products under registration.
- Management of the process to ensure that specifications are complete, comprehensive, and accurate, including obtaining input from all relevant governmental bodies, technical specialists, and program staff.

A component of Element 2 that is dependent on the activity of others:

- Product selection and quantity, as determined in Element 1.

2. Considerations

The main considerations for Element 2 are:

a. Overarching Principles of Quality and Timeliness

- Safety, efficacy requirements, and QA criteria must be clearly stated in the specifications.
- Specifications must be defined at the front end of the procurement process. Timely release of specifications is required to prevent delays in procurement.

b. Critical Component: Approval of Specifications

- Without completed and approved specifications, procurement cannot go forward.

c. Required Input From Other Elements

- Items, quantities, and delivery dates desired, as determined in Elements 1 and 4.

d. Key Decision Points

- Methods for development of product specifications.
- Format and content: product information, QA requirements, and packaging and shipping requirements.

e. Expected Output

- Completed and approved specifications ready to be included in bidding documents.

3. Challenges

Three main challenges are inherent in Element 2:

- Establishing a clear and effective process for developing specifications that ensures participation and approval of all relevant parties.
- Presenting requirements in a concise, thorough, and easily understood manner.
- Ensuring that technical specifications are "product neutral" through the use of generic terms and relative characteristics.

D. Technical Specifications

Technical specifications are one of the most important elements of procurement:

- They provide detailed information to suppliers about the goods to be purchased.
- They are the benchmarks against which the purchaser will judge the technical responsiveness of suppliers' bids.
- They form the basis for the contractual obligation of the supplier to the purchaser.
- They are the criteria against which the purchaser will determine the acceptability of specific goods prepared by the supplier for shipment.

Technical specifications must be clear, accurate, and complete; otherwise, the procurement will not be able to proceed on schedule and the entire procurement process may need to be cancelled. For example:

- Questions raised by suppliers can force the procuring entity to delay the deadline for bid submission to accommodate amendments to the bidding documents.
- A significant number of suppliers may misunderstand the requirements and quote items that do not meet program needs, forcing the procuring entity to reject all bids and restart the process.
- It may be impossible for the evaluation committee to correctly identify a winning bid, and if one is chosen for any other reason than what is specifically stated in the bidding documents, supplier protests may result.
- Goods that do not meet program needs may be delivered because the supplier is under no obligation to supply goods other than what is specifically described in the technical specifications included in the contract.

Under any of the above scenarios, time and resources will be wasted—at a minimum, the delivery schedule will be delayed. More importantly, needs will not be met, legal problems may ensue, misprocurement may be declared, and funding may be lost.

In addition to specifications that are clear, accurate, and complete, public-sector procurement requires that specifications be prepared in a way that will encourage maximum competition. They must be "product neutral." In other words, they must use generic terms, relative characteristics, and performance requirements rather than brand names and superficial descriptions. If there is no way to avoid stating a brand name, it must be followed by "or equivalent." Nonfunctional requirements such as color and exact dimensions must

have strong justification and may not be used simply to eliminate all but a specific brand. Specifications must be written in industry-standard vocabulary so there is no question about what is required.

A well-designed, comprehensive procurement specification is a health program's first line of protection against:

- Counterfeit products.
- Shelf-life limitations: expired or near expiry date products sold at very low prices, usually by unscrupulous middlemen.
- Deterioration due to temperature extremes during transit.
- Substandard products due to poor manufacturing processes.
- Mix-ups in warehouses or health facilities due to unclear labeling.

E. Methods for Development of Product Specifications

It can be challenging for some procurement units to determine how to develop or obtain appropriate specifications, and/or to decide who should prepare them. Considering the depth of knowledge and specialized information required for writing effective, unambiguous procurement specifications, it is a job best done by a person with specific technical expertise. Program staff are aware of their requirements from the standpoint of using a product, but they may not be familiar with the scientific terms and product and performance characteristics needed to accurately describe it.

The role of procurement staff in specification development involves gathering information, facilitating communication between technical personnel and end users, consulting with technical experts, and placing the completed specification in the bidding documents and Requests for Quotation that are released to suppliers. Writing the actual specifications is not a job for procurement officers.

Procurement staff also should be aware of the registration status of the RH products they are procuring. Most RH products that are imported must be approved by the regulatory authority of the exporting country as well as the regulatory authority of the importing country. A specification should identify the national regulatory requirements with which the RH product will be required to comply. If an RH product has not been approved (registered) by the national regulatory authority of the importing country, the time required to secure this approval can be significant, and the procurement staff will need to factor additional time for regulatory approval into their planning timeline. For additional information on the role of the national regulatory authority in the procurement process, see Supplementary Topics, Section K: Regulatory Authorities.

Specifications that have been developed in the past and preserved in a file or database for future use are very convenient; however, a technical expert should be asked to review them to make sure they accurately and completely reflect the *current* requirement before they are adopted for use in a procurement action. Many draft specifications for RH commodities are readily available, either in-country from earlier procurements or provided by the World Health Organization (WHO) and the United Nations Population Fund (UNFPA). These can provide an excellent starting place. The more challenging aspect may be the organization of the development process itself.

There is not a single recognized best practice for specifications revision or development, although most countries use similar approaches that rely heavily on input from varied contributors. A 2006 survey carried out by the United States Agency for International Development (USAID) DELIVER | PROJECT identified various methods used to develop product specifications in USAID priority countries.[1] A theme common to all approaches is the inclusion of program staff. The following summarizes the process in select countries:

Egypt: The logistics unit prepares technical specifications. Typically, the product specifications have been in circulation for years and need only be reviewed by experts in the particular field. Recently, specifications for family planning products were developed with technical assistance from the DELIVER PROJECT.

Ghana: The procurement and supply division in the Ministry of Health works with each program unit (e.g., maternal and child health and tuberculosis) to develop specifications.

Jordan: The contraceptive specification committee—with members representing the logistics unit in the maternal and child health department, the Jordan food and drug administration, the RH program, and others—are responsible for developing contraceptive product specifications.

Mali: A commission establishes product specifications for all essential medicines. The commission meets semiannually and includes representatives from all technical departments of the Ministry of Health.

Nepal: Program managers prepare specifications and quantify needs in collaboration with the logistics management division. In some cases—for example, malaria drugs—a technical subcommittee is assigned.

Nicaragua: The Directorate of Health Resources guides all drug and nondrug consumables. A technical unit within the directorate works with program staff to prepare the specifications.

The key to a successful process is ensuring that both technical experts and program staff are included in the development process and that all parties are given ample time and opportunity for clear communication.

[1] Rao R, Mellon P, Sarley D. *Procurement Strategies for Health Commodities: An Examination of Options and Mechanisms Within the Commodity Security Context*. Arlington, VA: United States Agency for International Development DELIVER PROJECT; 2006.

F. Format and Content

Failure to develop accurate specifications can result in the procurement of unsuitable products. A set of precise and clear specifications is a prerequisite for bidders to respond realistically and competitively to the requirements of the purchaser. The specification format should be comprehensive so that all important product features and requirements are addressed. The specification content should be clear and accurate to ensure the required product obtained is of good quality.

1. Format

Potential suppliers are required to comply in full with all stated product specifications. To avoid confusion or misunderstanding, specifications should be presented in a manner that clearly categorizes and delineates all requirements. Sample specifications showing examples of format and presentation are included in Section G of this module.

2. Content

Content of technical specifications can be divided into three broad categories: product information, QA provisions, and packaging requirements. Specific details to be addressed within each category will differ for each commodity; however, the following can be used as a general outline.

a. Product Information

- Generic name or international nonproprietary name.
- Presentation, strength, and quantity in each container.
- Color and size.
- Regulatory requirements:
    - Certificate of licensing.
    - Compliance with cGMPs.
    - Quality certification of all raw materials.
    - WHO prequalification (if required).
    - Lots per order.
    - Shelf life.

b. Quality Assurance Provisions

- Documentation: all documents, such as manufacturing records and Certificate of Analysis, to be provided by the manufacturer.
- Inspection by the purchaser: the rights and timing for inspection of goods, if requested by the purchaser.
- Sampling procedures: the steps of the product sampling procedure, if requested by the purchaser.
- Sample retention: the manufacturer's requirements to retain samples from manufacturing lots.

c. Packaging and Shipping Requirements

- Primary container: requirements of the primary container specific to the commodity.
- Labeling: all information to be included on the product label, including but not limited to:
    - Product/brand name.
    - Lot/batch number.
    - Expiration date (month and year).
    - Date of manufacture.
    - Manufacturer's name and address.
    - Contents and quantity, including tablet formulation (amounts of active ingredients per tablet).
    - Drug registration number (if applicable).
    - Brand or company logo.
    - Country of origin.
- Product information sheets: language, quantity, and placement of product information sheets for consumers and physicians.
- Inner boxes: packaging material, size, and quantity of inner boxes.
- Exterior shipping cartons: type and strength of cartons necessary to protect commodities during shipment.
- Markings: markings and information required on inner and outer cartons.

G. Sample Specifications

1. Checklist

Checklist of Elements for Inclusion in Specifications for Pharmaceuticals and Contraceptives

- ☐ **Description:** Generic name (INN); Type of product; Intended use
- ☐ **Formulation (drug content):** Pills & Injectables
- ☐ **Materials:** Condoms & IUDs
- ☐ **Presentation:** Dosage form; Dosage size
- ☐ **Filling Volume (as applicable)**
- ☐ **Identification (markings):** Marking/labeling of product
- ☐ **Primary Packaging:** Materials and description; Package layout/dimensions; Markings; Special labeling/logo (if desired)
- ☐ **Overpacking (cartons):** Materials and description; Markings
- ☐ **Exterior Packing (for shipping):** Materials and description; Markings
- ☐ **Shelf Life:** In months or years; Stability/storage temperature; Months remaining upon receipt in-country
- ☐ **Printed Materials:** Language; Patient inserts; Physician inserts; Special instructions
- ☐ **Regulatory Requirements**
- ☐ **Quality Assurance Requirements:** Pharmacopoeia standard (if applicable)
- ☐ **Documentation:** Test data; Certificate of Analysis; Regulatory certificates
- ☐ **Quality Compliance Provisions:** Preshipment inspection (of physical attributes); Preshipment sampling and testing (for analysis of suspect products)

INN: International nonproprietary name.
IUD: Intrauterine device.

2. Documents

Exhibit 2-1

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

The following is a sample format for use in devising procurement specifications for oral contraceptives. *Examples of actual product specifications are in italics. When preparing procurement specifications, appropriate product specifications should be substituted for the italicized examples.* This sample is designed to be used in conjunction with bidding and contract documents.

Information for submission of samples

The sample oral contraceptives submitted by the Bidder in response to this Invitation for Bids must be exactly the same[2] as would be supplied if a contract were awarded to the Bidder. The packets containing the product need not have a printed logo as stipulated under Clause 1.12 of this specification; however, other information as stipulated under the aforementioned clause must be furnished. For sample submission only, this information (logo optional) may be printed on a sticker and affixed to the packets containing the product.

1. Requirements

Oral contraceptive tablets in accordance with the following specifications:

- *Twenty-eight (28)-day cycle package consisting of twenty-one (21) oral contraceptive norgestrel and ethinylestradiol tablets and seven (7) ferrous fumarate tablets.*

Contraceptive tablets: 21

Each tablet shall contain 0.03 mg of ethinylestradiol and 0.3 mg of norgestrel.

Spacing tablets: 7

Each tablet shall contain 75 mg ferrous fumarate.

1.1 Product and Brand Names

Product name: _____

Brand names: _____

_____

[2] For example, same tablet shape, color, weight, ingredients, and identification imprint; same blister pack size, material, text, and identification markings; same inner box size, material, text, and identification markings.

1.2 Raw Materials

Oral contraceptives offered under this purchase description shall be produced from validated raw materials obtained from a licensed manufacturer or its authorized distributor.[3]

1.3 Registration Requirements

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

1.4 Certificate of Licensing Status

Oral contraceptives offered under this purchase description shall be licensed for marketing by the drug regulatory authority of the country of origin. Prior to award of the Contract, the successful offeror(s) may be required to submit a "statement of licensing status of pharmaceutical product(s)" as provided under the World Health Organization (WHO) Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce.[4]

1.5 No Objection Certificate

In the case of goods of foreign origin, oral 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.

1.6 Compliance With Current Good Manufacturing Practices

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

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[3] Because the raw materials that make up both active and inactive ingredients are of great importance for final product bioavailability and stability, current good manufacturing practices require that manufacturers validate vendors for all raw materials. A typical validation includes, but is not limited to, these areas:

- **Manufacturing records and procedures for raw materials synthesis, processing, packing, and storage.**
- **Quality control records and procedures for the raw materials, in-process, and final product.**
- **Plant certification by local regulatory authorities (such as commerce, industry, health, labor, environment) as required.**
- **Certification of workers' training in current good manufacturing practices and safety protection.**
- **Records demonstrating raw materials with the required physical and chemical characteristics.**

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

1.7 WHO Certification—Movement in International Commerce

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

1.8 Shape and Dimensions

Tablets shall be of the shape and dimensions of the Bidder's normal, standard commercial tablet.

1.9 Colors

Contraceptive and ferrous fumarate (or inert, if applicable) tablets shall be similar to Bidder's normal, standard commercial tablets.

1.10 Tablet Markings

Each tablet shall bear the identifying imprint of its manufacturer.

1.11 Packaging

1.11.1 Monthly Cycle Presentation

Each individual tablet shall be enclosed in a transparent blister pack of thermoformed polymer, with a minimum thickness of 0.1905 mm (.0075 inch) backed with aluminum foil, minimum thickness 0.0178 mm (0.0007 inch). Variations must be proven scientifically comparable by means of stability data.

The size of the package shall not be less than 57.15 mm (2.25 inches) x 82.55 mm (3.25 inches). Thicker polymer or foil or the addition of a card to either the front or the back of the package (in addition to the minimum polymer or foil) is acceptable.

1.11.2 Mounting

Tablets shall be mounted on four (4) rows of seven (7) tablets per row. Contraceptive tablets shall precede the ferrous fumarate tablets (or inert tablets, if applicable).

1.12 Identification Markings on Individual Blister Packs

Each individual blister pack shall have the following information:

- Product/brand name.
- Lot/batch number.

- Expiration date (month and year).
- Date of manufacture.
- Manufacturer's name and address.
- Arrow indicating sequence of tablets.
- Contents and quantity, including tablet formulation (amounts of active ingredients per tablet).
- Drug registration number (if applicable).
- Family planning logo (if applicable).
- Made in _____.
- Product use and storage instructions (accompanying the blister pack).

1.12.1 Printing and Layout

On the front of each monthly cycle above the first row of tablets and in the left-hand corner, the trade or brand name of the product shall be printed in precision full registration. In parentheses, in reduced lettering (smallest type no less than 1 mm high) and below the product or brand name, shall be printed "Family Planning Pills." Sequence of administration shall be clearly indicated by an arrow/line pathway on the unit.

The month and year of expiration and the lot/control number shall be shown in Arabic numerals; for example, 6/11 will indicate the product expires in June 2011. Debossing is acceptable for these numbers.

The tablet formulation and a "copy control code" (evidence that artwork/packaging has been approved by all parties) shall be printed on the individual packet and may be printed on the reverse side (smallest type no less than 1 mm high).

1.12.2 Color

Background color shall be the natural color of the aluminum foil on the face, with a dark blue (PMS Blue 301) stripe across the top and the "Blue Lady" symbol depicted to the right but within the blue stripe. The reverse of the individual packet will not be inked except for necessary printing.

1.13 Workmanship

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

1.14 Lots Per Order

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

1.15 Shelf Life

The shelf life of the product provided under this solicitation shall be *five (5) years* from the date of manufacture when stored under tropical conditions such as those prevailing in _____ *(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 *five (5)-year* shelf life at ambient temperatures at or greater than 32 degrees Celsius and at a relative humidity of 85% in the proposed blister package.

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

1.16 Test Data

Chemical and physical test data for raw materials, components in-process, and finished product testing must be on record for each lot 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[5] of the satisfaction of the technical specification requirements for which specific inspection instructions or protocols have not been provided. Such evidence is contained in the "Manufacturer's Batch Certificate" under the WHO Certification Scheme.

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

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[5] Evidence includes 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.[6]

The Purchaser may have some or all of the tests specified in Section _____ of 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.

When 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.

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[6] **Depending on the tests required, sampling may be conducted according to the standards of the International Organization for Standardization (ISO 2859: Inspection by Attributes) (included as Appendix III.H), the report of the WHO Expert Committee on Specifications for Pharmaceutical Preparations (included as Appendix III.I), or as dictated by local or international pharmacopoeia. Following recognized sampling procedures helps to ensure that the products tested are representative of the whole.**

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) cycles, or the equivalent required to perform three (3) complete chemical assays, from each lot shipped, for a period of one (1) year after the printed expiration date.

3. Packing

3.1 Inner Boxes

3.1.1 Products sealed in individual packets as specified in Section 1.11 shall be packed in inner boxes of *one hundred (100) cycles.*[7]

Inner boxes shall be made of *light fiberboard (white)* of a size sufficient to contain the specified number of cycles. The overall dimensions should be such that the product does not get damaged during transportation and storage.

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

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

3.2 Exterior Shipping Cartons

3.2.1 *Product and printed materials, packaged and packed as specified above, shall be contained in triple-wall corrugated fiberboard cartons made from weather-resistant fiberboard with a bursting test strength of not less than 1,900 kPa. The carton flaps shall be secured with water-resistant adhesive applied to not less than 75% of the area of contact between the flaps or with 75 mm-wide water-resistant tape applied to the full length of the center seams and extending over the ends not less than 75 mm.*[8] *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.*

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[7] **Sometimes oral contraceptives are packaged to contain three (3) cycles per inner box. If this is the preferred configuration, a three (3)-cycle-per-box packaging description should be detailed in the specification.**

[8] **The use of additional tape along the joint of the outer lids and around the top and bottom corners will greatly increase each carton's resistance to damage during shipment and storage. Tape can be made of plastic film, kraft paper, or fabric, either plain or reinforced with plastic threads.**

3.2.2 The Bidder shall fill in the following blanks:

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

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

3.3 Markings

3.3.1 Inner Boxes

The inner boxes shall be marked with the following information in a clearly legible manner that is acceptable to the Purchaser[9]:

- 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 for storage and handing.

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.[10]

Regulatory information (on two opposing sides of carton)

- Product/brand name.
- Lot/batch number.

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

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

- 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

3.4.1 *Consumer information and directions for use shall be printed in English and/or in _____ and provided as package inserts, one copy for each consumer unit. All copies are to be accumulated, fastened together, and included in each exterior shipping carton.*

3.4.2 *Information for physicians' use shall be printed in English and/or in _____. Two copies of such information shall be provided for each one thousand two hundred (1,200) monthly cycles and shall be placed in each exterior shipping carton.*

<u>Inspection Sampling and Testing—Oral Contraceptives</u>

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

1.1 Packaging, Packing, and Markings

a. One hundred percent (100%) of the exterior 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 packages will be drawn from the exterior shipping cartons at General Inspection Level II, or, at the discretion of the Purchaser, General Inspection Level III, Single Sampling Plan for Normal Inspection.*

The sample will be examined for:

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

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

1.2 Tablet

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

Pharmacopoeial tests:

- Identification.
- Assay of active ingredient(s).
- Content uniformity.
- Disintegration and/or dissolution.
- Uniformity of mass (not required if content uniformity test performed).

Nonpharmacopoeial tests:

- Package seal integrity test.[11]

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

[11] **Immerse package in 0.05 percent methylene blue solution under 15 vacuum gauge for two minutes. Observe for leakage. AQL 2.5%.**

performed, their specifications, and actual test results obtained. All pharmacopoeial test results shall meet applicable pharmacopoeial limits.

1.3 Resolution of Defects

a. Packaging, Packing, and Markings

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

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

b. Tablet

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

1.4 Visual Inspection Review Guidelines for Oral Contraceptives

Oral contraceptives come in cycles of 21 or 28 tablets. In the 28-day cycles, 7 placebo or iron tablets are provided in addition to the contraceptive tablets. Iron tablets generally are larger and brown in color. Most oral contraceptives are packaged in blister packages with a cardboard overpack. Frequently, 3 cycles are packaged together in a sealed foil overpack. Oral contraceptive shelf life ranges from 3 to 5 years at 37 degrees Celsius, although the majority of brands have a 5-year shelf life. Blister packaging provides good protection from adverse environmental conditions.

The following list of labeling criteria is 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 following labeling criteria listed 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—oral 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
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
Arrow indicating sequence of pills	☐	☐	☐	Critical

Visual Inspection Criteria	Meets Criteria Yes	No	n/a	Defect Classification
Contents and quantity	☐	☐	☐	Major
Drug registration number	☐	☐	☐	Major
Storage instructions	☐	☐	☐	Minor
Print on unit package is legible	☐	☐	☐	Minor
Product use instructions properly folded	☐	☐	☐	Minor
Unit Package Condition/Content:				
Unit pack in good condition (undamaged, unopened)	☐	☐	☐	Critical
Pills in good condition (unbroken, correct color, none missing)	☐	☐	☐	Critical
Good package seal, no breaks	☐	☐	☐	Critical
Unit package contains no foreign matter	☐	☐	☐	Critical

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%.	

Exhibit 2-2

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

The following is a sample format for use in devising procurement specifications for injectable contraceptives. *The example presented here is for the long-acting injectable contraceptive medroxyprogesterone acetate. Examples of actual product specifications are in italics. When preparing procurement specifications, appropriate product specifications should be substituted for the italicized examples.* This sample is designed to be used in conjunction with bidding and contract documents.

Information for submission of samples

The sample injectable contraceptives submitted by the Bidder in response to this Invitation for Bids must be exactly the same as would be supplied if a contract were awarded to the Bidder.[12] 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: _____

[12] **For example, vials or ampoules must be of the 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.**

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.[13]

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 Contract, the successful offeror(s) may be required to submit a "statement of licensing status of pharmaceutical product(s)" as provided under the World Health Organization (WHO) Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce.[14]

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.

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[13] **Because the raw materials that make up both active and inactive ingredients are of great importance for final product bioavailability and stability, current good manufacturing practices require that manufacturers validate vendors for all raw materials. A typical validation includes, but is not limited to, these areas:**

- **Manufacturing records and procedures for raw materials synthesis, processing, packing, and storage.**
- **Quality control records and procedures for the raw materials, in-process, and final product.**
- **Plant certification by local regulatory authorities (such as commerce, industry, health, labor, environment) as required.**
- **Certification of workers' training in current good manufacturing practices and safety protection.**
- **Records demonstrating raw materials with the required physical and chemical characteristics.**

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

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 (cGMPs). Such certification can be found in the WHO Certification Scheme "Certificate of Pharmaceutical Product." Supplier also must be able to provide copies of its annual cGMP audit reports.

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[15] of the satisfaction of the technical specification requirements for which specific inspection instructions or protocols have not been provided. Such evidence is contained in the "Manufacturer's Batch Certificate" under the WHO Certification Scheme.

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

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.[16]

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

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[15] **Evidence includes quality control and manufacturing records, in-process control records, and final product Certificate of Analysis.**

[16] **Depending on the tests required, sampling may be conducted according to the standards of the International Organization for Standardization (ISO 2859: Inspection by Attributes) (included as Appendix III.H), the report of the WHO Expert Committee on Specifications for Pharmaceutical Preparations (included as Appendix III.I), or as dictated by local or international pharmacopoeia. Following recognized sampling procedures helps to ensure that the products tested are representative of the whole.**

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.

When 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 Bidder shall fill in the blanks provided below:

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

3.2 Exterior Shipping Cartons

3.2.1 *Product and printed materials, packaged and packed as specified above, shall be contained in triple-wall corrugated fiberboard cartons made from weather-resistant fiberboard with a bursting test strength of not less than 1,900 kPa. The carton flaps shall be secured with water-resistant adhesive applied to not less than 75% of the area of contact between the flaps or with 75 mm-wide water-resistant tape applied to the full length of the center seams and extending over the ends not less than 75 mm.*[17] *Plastic strapping shall be placed around the carton, with a minimum of two crossing bands. Cartons exceeding 760 mm (30 inches) in length shall have additional bands placed around the carton.*

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

3.2.3 The Bidder shall fill in the following blanks:

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

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

3.3 Markings

3.3.1 Inner Boxes

The inner boxes shall be marked with the following information in a clearly legible manner which is acceptable to the Purchaser[18]:

- Product/brand name.
- Lot/batch number.
- Expiration date (month and year).
- Date of manufacture.
- Manufacturer's name and address.

---

[17] **The use of additional tape along the joint of the outer lids and around the top and bottom corners will greatly increase each carton's resistance to damage during shipment and storage. Tape can be made of plastic film, kraft paper, or fabric, either plain or reinforced with plastic threads.**

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

- Contents and quantity.
- Drug registration number (if applicable).
- Instructions for storage and handing.
- Formulation and presentation.

3.3.2 Exterior Shipping Cartons

The following information shall be stenciled or labeled on the exterior shipping cartons on two opposing sides in bold letters at least _____ mm high with waterproof ink in a clearly legible manner that is acceptable to the Purchaser.[19]

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.

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

- Quantity of goods.
- Carton _____ of _____.

3.4 Printed Materials—Product Information Sheets

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

Inspection Sampling and Testing—Injectable Contraceptives

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

1.1 Packaging, Packing, and Markings

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

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

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

The sample will be examined for:

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

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

1.2 Injectable

At the discretion of the Purchaser, part of the selected sample may be sent to a qualified 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 test results shall meet applicable pharmacopoeial limits.

1.3 Resolution of Defects

a. Packaging, Packing, and Markings

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

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

b. Injectable

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

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. The manufacturer's recommended storage conditions should be followed.

The following list of labeling criteria is 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 following labeling criteria 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

Visual Inspection Criteria	Meets Criteria Yes	No	n/a	Defect Classification
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
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%.	

H. Reference Material

1. Websites

***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/

WHO is in the process of developing a sample specification for an intrauterine device (IUD) that is similar in format to the specification developed for male latex condoms. Once the IUD specification is completed, it will be placed on the WHO website.

***Essential Medicines for Reproductive Health: Guiding Principles for Their Inclusion on National Medicines Lists* (PATH/WHO/UNFPA, 2006)**

This document provides an overview of the process for including RH medicines on national essential medicines lists at the country level based on the essential medicines concept. This guide presents the rationale for including information on 16 specific RH medicines on national essential medicines lists. While this document does not contain procurement specifications, it does contain a policy brief for each of the 16 RH medicines that includes information on product background, evidence summary, and indications and dosage, as well as remarks that provide helpful general information on the product.

http://www.who.int/reproductivehealth/publications/general/a91388/en/

I. Learning Evaluation

1. Who should be involved in the development and approval of specifications for RH commodities?

2. Give five examples of general product information that should be included in a specification for RH commodities.

3. Give five examples of packaging and shipping requirements that should be included in a specification for RH commodities.

4. How does a strong specification ensure the quality of RH commodities?

5. Name two sources for sample specifications for RH commodities.

6. What is a "product-neutral" specification? What type of information should be included to ensure that a specification is product neutral?

Learning Evaluation Answers

1. There is not a single best practice for developing specifications for RH commodities. In most countries, the approach taken is to include input from several contributors. Program staff can contribute information on general requirements; however, a person with specific technical expertise on the product is in the best position to take the lead on developing a product specification. Procurement staff do not write specifications, but can gather information, facilitate communication between technical personnel and end users, and arrange for the specification to be formatted and placed in the bidding documents. The key to a successful process is to ensure that both technical experts and end users are included in the specification development process and that all parties are given ample time for clear communication. See Section E.

2. The following general product information should be included in a specification for RH commodities:

   - Generic name or international nonproprietary name.
   - Presentation, strength, and quantity in each container.
   - Color and size.
   - Regulatory requirements.

   See Section F.2.a.

3. The following packaging and shipping requirements should be included in a specification for RH commodities:

   - Primary container: requirements of the primary container specific to the commodity.
   - Labeling: all information to be included on the product label, including, but not limited to:
     - Product information sheets: language, quantity, and placement of product information sheets for consumers and physicians.
     - Inner boxes: packaging material, size, and quantity of inner boxes.
     - Exterior shipping cartons: type and strength of cartons necessary to protect commodities during shipment.

- Markings: markings and information required on inner and outer cartons.

See Section F.2.c.

4. A well-designed, comprehensive procurement specification helps ensure the quality of RH commodities by providing protection against:
   - Counterfeit products.
   - Shelf-life limitations: expired or near expiry date products sold at very low prices, usually by unscrupulous middlemen.
   - Deterioration due to temperature extremes during transit.
   - Substandard products due to poor manufacturing processes.
   - Mix-ups in warehouses or health facilities due to unclear labeling.

   See Section D.

5. A sample specification for male latex condoms can be found on the following WHO website:

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

   WHO is in the process of developing a sample specification for an IUD that is similar in format to the specification developed for male latex condoms. Once the IUD specification is completed, it will be placed on the WHO website. See Section H.

6. A "product-neutral" specification is a generic specification that does not incorporate any specific information and requirements that would limit competition to a single product. It is written in a way to encourage maximum competition. It must use generic terms, relative characteristics, and performance requirements rather than brand names and superficial descriptions. If there is no way to avoid stating a brand name, it must be followed by "or equivalent." See Section D.

J. 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. Product specifications for RH commodities are reviewed and approved by technical experts.

2. Percentage of product specifications that are product neutral.

3. Percentage of RH product specifications using a format with clear and comprehensive requirements in the key categories:
   - Product information (generic name, strength and quantity, color and size, and shelf life).
   - Registration requirements.

4. Percentage of bids utilizing QA provisions in each of the following areas for the RH commodities selected:
   - Sampling.
   - Inspection.
   - Testing requirements.
   - Documentation requirements.

5. Percentage of bids with specifications that include information on packaging and shipping requirements (primary container requirements, labeling requirements, exterior shipping carton requirements, and marking requirements).

K. Glossary and Acronyms

AIDS	Acquired Immunodeficiency Syndrome.
AQL	Acceptable quality limit: The lowest allowable limit of quality in a lot.
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.
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.
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.

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.
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.
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).
Expiration (Expiry) date	The date beyond which the manufacturer will not guarantee the product.
Formulation	The amounts of active ingredients per tablet.
HIV	Human Immunodeficiency Virus.
Injectable	Injectable contraceptive.

INN	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.
IUD	Intrauterine device.
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).
Manufacturer's Batch Certificate	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.
Marks, markings	An application of numbers, letters, labels, tabs, symbols, or colors for handling or identification during shipment and storage.

Misprocurement	A declaration that goods have not been procured according to the agreed procedures in the loan agreement.
N/A (n/a)	Not applicable.
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.
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.
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.
Phase	A natural division of the ten elements of the supply process into three sequential parts: program planning, procurement process, and contract performance.
Procurement method	Process a purchaser uses to reach an agreement with a seller.
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 (see Module 4 for more details), 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.
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.
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.
Specification	A definitive description of the commodity to be procured.
Standard	Establishes the minimum level of performance and safety requirements for the product, and generally specifies methods of use when carrying

	out basic tests for quality verification. Standards are traditionally developed and published by international and national regulatory authorities or standards bodies.
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.
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.
USAID	United States Agency for International Development: An independent federal government agency that receives overall foreign policy guidance from the Secretary of State. Its work supports long-term and equitable economic growth and advances United States foreign policy objectives by supporting economic growth, agriculture, and trade; global health; and democracy, conflict prevention, and humanitarian assistance.

USAID | DELIVER PROJECT	A United States Agency for International Development-funded project that strengthens supply systems for essential health commodities and works to ensure their sustainability.
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.
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.