9 Contract Performance and Monitoring

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 9 of the reproductive health (RH) supply process. It describes the activities that begin after the contract between the purchaser and supplier has been signed and payment arrangements are in place (Element 8) and concludes when the RH commodity is received at the port of entry (for imported commodities) or at the central warehouse (for local commodities).

Contract management and supplier performance monitoring are important components of the procurement process, since unsatisfactory performance by the supplier can jeopardize the objectives of an RH program. Proactive contract management and performance monitoring that engages the supplier's support allows the purchaser to obtain information on supplier production and performance problems at an early stage in their development. Early identification improves the chances of resolving a problem before it significantly impacts the product delivery schedule. It can also be more cost effective, since early problem identification allows the purchaser and supplier to consider a broader range of contingency options, thereby minimizing the need to resort to more costly solutions such as expedited shipments or overtime labor.

One of the key activities available to the purchaser in monitoring the supplier's requirement to provide a good-quality product is to conduct preshipment compliance. The three levels of preshipment compliance most often used by purchasers (document review, visual inspection, and laboratory or physical testing) are discussed in this module.

The purchaser should also monitor the transport arrangements made for the product, particularly for those products that may have temperature storage limitations.

Finally, the module also discusses the purchaser's responsibility to manage the contract payment process, including completing timely payment arrangements once the supplier has fulfilled its contract obligations.

B. Learning Objectives

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

- Discuss the objectives of a contract performance monitoring system and scorecard.
- Develop a contract performance monitoring scorecard.
- Identify the benefits of preshipment compliance.
- Name different levels of preshipment compliance.
- Discuss key issues in product transport.
- List the benefits of managing supplier payments.

C. Components, Considerations, and Challenges

1. Components

The four main components of Element 9 are:

- Establishing and utilizing a contract performance monitoring system.
- Arranging for appropriate preshipment compliance.
- Managing provisions to protect goods during transit.
- Managing supplier payments.

The purchaser is responsible for these components, while the supplier is responsible for producing and delivering RH commodities in compliance with the contract requirements.

2. Considerations

The main considerations for Element 9 are:

a. Overarching Principles of Quality and Timeliness

- Performance monitoring, including preshipment compliance, helps provide evidence of product quality prior to shipment and payment.
- Performance monitoring identifies supplier problems at an early stage, allowing the purchaser an opportunity to mitigate impact to the RH program.
- Appropriate transport provisions can protect the product during shipment.
- Effectively managing payments can promote supplier performance.

b. Critical Component: Supplier's Production of Good-Quality Reproductive Health Commodities

- If the supplier encounters production problems that delay delivery, or produces a commodity that does not meet specifications, implementation of the RH program can be jeopardized.

c. Required Input From Other Elements

- Product specifications, as determined in Element 2.
- Delivery requirements and appropriate terms and conditions from the bidding documents (Element 6) and the contract (Element 8).

d. Key Decision Points

- The extent to which contract performance monitoring should be conducted.
- The level of preshipment compliance to use.

e. Expected Outputs

- Contract performance monitoring scorecard.
- Improved supplier performance.
- On-time delivery of good-quality RH commodities per the contract requirements.

3. Challenges

The main challenges inherent in Element 9 are:

- Eliciting supplier commitment to take contract compliance and monitoring seriously.
- Proactive implementation of contract performance monitoring by the purchaser, including selecting the correct key measures, obtaining the required data, and properly using the data to improve supplier performance.

D. Contract Performance Monitoring

The key objectives of a contract performance monitoring system are to:

- Ensure that all technical specifications and contract requirements are met.
- Identify performance problems early and correct them.
- Provide information on a supplier's performance when considering the supplier for future contracts.

By establishing a monitoring system to achieve these objectives, the purchaser strengthens its ability to successfully support the program for which the commodities have been ordered. Setting up and properly implementing an effective performance monitoring system, however, requires a commitment of both time and resources.

The basic components of a performance monitoring system include:

- Formal procurement records and key performance indicators.
- Supplier commitment to meet the contractual requirements that form the basis for the performance indicators.
- Procedures for addressing performance problems and contract disputes.
- Preshipment compliance plan.
- Procedures for monitoring commodity transport.

Each of these components is discussed in the following sections.

The extent to which performance monitoring systems are used is determined by the purchaser on the basis of risk-management and cost-benefit assessments. For example, when the commodity being purchased has a high relative expenditure cost and the supply is difficult to secure, then the priority would be to establish a robust contract performance monitoring system to manage the risk associated with the procurement. Most health care commodities are of high value and the risks associated with poor-quality products necessitate using a robust performance monitoring system.

Regardless of the value of the procurement, it is always important to ensure that the product meets basic requirements. For RH commodities, where the overall risk to health and program implementation from poor-quality products is high, the purchaser should

establish and implement a thorough contract performance monitoring system to help manage the risk.

The following discussion on development of a contract monitoring system assumes a high-value procurement of a limited-supply RH commodity.

1. Developing a Contract Performance Monitoring System—Supplier Scorecard

The key components required to develop a contract performance monitoring system are:

- Formal procurement records.
- Key performance indicators.

a. Formal Procurement Records

The formal procurement record is a set of files containing all the critical documents and information pertinent to the procurement contract. It is from the procurement record that the purchaser draws relevant information (such as product technical specifications, delivery quantities, and schedules) that is used to develop a contract performance monitoring system.

The key activities in establishing a formal procurement record are:

Setting up a separate set of procurement files for each procurement
Each contract should have its own procurement record files. This allows for easier access to information critical to the contract.

Including all pertinent documents and information
For the procurement record files to be of value, they should include all of the key documents, approvals, and information relevant to the procurement transaction. See Exhibit 9-1 in Section H.1 for a list of documents and information that can be included in procurement record files, and Supplementary Topics, Section J: Recordkeeping, for more information.

Retaining procurement records for a required length of time
The purchase contract is a legal document identifying the contractual rights and obligations of each party to the contract. The contract and procurement record files should be kept for the period of time required by national regulations and organizational requirements.

Formal procurement record files serve three useful purposes:

- The procurement record provides essential supporting evidence in the event that it becomes necessary to take legal action against the supplier.
- The procurement record helps to provide a full audit trail.
- The information contained in the procurement record can be used to help evaluate a supplier's past performance and if additional opportunities to conduct business with the supplier should be considered.

b. Key Performance Indicators

Key performance indicators are used to track and evaluate the supplier's performance in complying with the contract requirements. For performance indicators to be effective, they need to be SMART:

- **S**pecific
- **M**easurable
- **A**ttainable
- **R**elevant
- **T**ime based

A range of performance indicators can be developed to monitor a supplier's performance, and the exact indicators used will vary according to the commodity, the level of risk associated with contract failure by the supplier, and the value of the procurement. The specific information needed to develop performance indicators is drawn from the procurement record files discussed above. For most high-value RH commodity procurements, performance indicators should be developed that track compliance with the following categories:

- Technical specifications.
- Timeliness of deliveries.
- Labeling and packaging requirements.
- Shelf-life requirements.
- Contract terms and conditions.

See Exhibit 9-2 in Section H.1 for a sample performance monitoring checklist that includes a list of performance indicators for the general performance categories listed above, and Exhibit 9-3 for an example supplier performance scorecard.

2. Engaging Supplier Commitment to Support Performance Monitoring

For performance monitoring systems to operate effectively, the supplier must be notified that its contractual performance is being monitored and agree to provide key information to the purchaser. Ideally, the purchaser has engaged the supplier in a discussion on performance monitoring prior to contract signature.[1] In this discussion, the purchaser should share information on the key performance indicators being proposed and allow the supplier to contribute to the development of these indicators prior to inclusion in the contract. Allowing supplier participation in defining performance evaluation criteria can strengthen the working relationship with the supplier, and it can build supplier commitment to support the monitoring system by providing early notification of potential performance problems.

3. Addressing Performance Problems

If a performance problem is identified, it is in the purchaser's interest to take prompt action, since early intervention can often prevent a problem from becoming worse and developing into a legal dispute or jeopardizing the project.

The purchaser should take the following steps when a performance problem has been identified:

- **Review the procurement record files to identify each party's rights and obligations.** The contract will identify the remedial rights available to the purchaser and the responsibilities of the supplier. Before contacting the supplier, the purchaser should be clearly aware of the applicable contract conditions that allow for corrective measures to be taken under the contract. The purchaser should also review the conditions causing the problem and be sure that the purchaser has not contributed to the problem in any significant way.

[1] **See Module 8 for additional information on securing supplier commitment to performance monitoring.**

- **Formally notify the supplier that performance is not in compliance with contract requirements.** This notification should be in writing and should include the following information:
  - ***Identification of the problem:*** The problem should be clearly identified so there is no possibility of misunderstanding the situation on the supplier's part.
  - ***Identification of the corrective actions to be taken:*** The purchaser should ensure that any corrective action requested is within the bounds of its remedial rights under the contract. If necessary, the purchaser should seek legal advice to review the corrective action request.
  - ***Identification of the time frame allowed to the supplier to address corrective action:*** The purchaser should provide the supplier with a specific time frame for the supplier to investigate and provide its recommended remedy to correct the problem.
  - ***Identification of the consequences of failure to correct the performance problem:*** The purchaser should notify the supplier of the specific financial or contractual consequences of not addressing and correcting the performance issue.

A copy of the notification should be placed in the procurement record.

4. Contract Disputes

If the supplier does not accept the purchaser's request for corrective action, a contract dispute between the parties may result. Contract disputes can arise between the purchaser and seller for several reasons, including:

- Differing interpretations of technical specifications and requirements.
- Differing interpretations of contract terms and conditions.
- Impact of unplanned events.

If a dispute should arise, the purchaser should refer back to the contract provisions to identify the dispute resolution measures that are specified.

If alternative dispute resolution procedures are available, they should be considered, as they can provide a way to resolve disputes without incurring the expense of lawyers and courts. Alternative dispute resolution procedures include:

- Negotiation.
- Mediation.
- Expert appraisal/determination.
- Arbitration.

Dispute resolution procedures should be detailed in the contract with both parties' agreement. The dispute resolution options should be listed in order of precedence, and the least severe and least costly method should be attempted first, before resorting to more severe methods.

Any dispute, regardless of the method used to resolve it, takes time and incurs additional expense. As a matter of general practice, the purchaser is best advised to take practical measures during the contract preparation and monitoring process that can help to reduce the chances of a dispute. These measures include:

- Stating contractual requirements clearly (e.g., specifications, delivery dates, etc.).
- Using plain and clear language in all contract documents.
- Addressing problems as soon as they arise, before they escalate.
- Not allowing a pattern of supplier defaults to develop.
- Maintaining a good working relationship with the supplier.

For successful contract management, both the purchaser and the supplier must recognize that each has a major role to play in ensuring the successful performance of the contract. In addition to assessing the supplier's performance, there should be a mechanism in place to allow the supplier to assess the *purchaser's* performance in such areas as timely payments, equitable contract terms, etc.

E. Preshipment Compliance

One of the key activities available to the purchaser for monitoring a supplier's performance, particularly regarding the commodity's compliance with technical and quality assurance requirements, is the right to conduct preshipment inspection or testing of the commodity, also known as preshipment compliance. The purchaser reserves the right to conduct preshipment compliance by including the requirement in the bidding documents and the contract issued to the supplier.

It is often in the purchaser's best interest to have commodities inspected or tested before shipment. For imported commodities, identifying and resolving product problems prior to shipment (instead of identifying them upon arrival in-country) minimizes the impact on the delivery schedule and the program and saves shipping costs and time.

Some countries have established mandatory preshipment compliance requirements for goods, based either on the type of good or the value of the shipment. In most cases, the purchaser decides on the type or level of preshipment compliance that should be conducted for each product. At minimum, Level I document review should be conducted for all purchases.

The three basic levels of preshipment compliance are:

- Level I—Preshipment Document Review.
- Level II—Visual Inspection of Product.
- Level III—Laboratory or Physical Testing of Product.

1. Level I—Preshipment Document Review

At this level of preshipment inspection, the supplier submits the documents identified in the contract to the purchaser to review prior to shipment. These documents usually include:

- Certificate of Analysis for each manufacturing lot (batch) in the shipment. This could be the "Batch Certificate of a Pharmaceutical Product" used in accordance with the World Health Organization (WHO) Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce.[2]
- Packing list (identifies the quantity of goods in the shipment).

[2] See http://www.who.int/medicines/areas/quality_safety/regulation_legislation/certification/guidelines/en/index.html for additional information on the WHO Certification Scheme.

- Commercial invoice (identifies the value of the shipment).
- Certificate of Origin (identifies the country of manufacture).
- Other documents as requested by the purchaser.

The purchaser arranges for personnel with appropriate technical expertise to review the submitted documents to confirm that the required product tests were performed by the supplier during product manufacture and the reported test results meet the standards.[3]

2. Level II—Visual Inspection of Product

For visual inspection, the purchaser contracts a professional, independent inspection company to randomly select and visually inspect product samples to confirm that the following features comply with contract requirements:

- Product labeling.
- Product packaging.
- Shipping container markings.
- Product quantity.

Visual inspection will also reveal any signs of:

- Product damage or deterioration.
- Package damage.
- Poor workmanship.

The purchaser must provide specific instructions to the inspection company on how the inspection should be conducted. This is often done in the form of an inspection order. See Exhibit 9-4 in Section H.1 for a sample inspection order.

If visual inspection identifies any defects, the inspection company should assess and document the problem, including preparing a report that can be used to support the filing of a claim against the supplier if warranted. The purchaser's decision to accept or reject a shipment is based on comparing the inspection results to the product specifications (labeling, packaging, etc.) identified in the contract.[4]

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[3] From *Ensuring the Quality of Medicines in Resource-Limited Countries: An Operational Guide* (United States Pharmacopeia Drug Quality and Information Program and collaborators, 2007).

[4] See Module 2 for additional information on visual inspection guidelines.

3. Level III—Laboratory or Physical Testing of Product

Conducting laboratory or physical testing of a product is done on a selective basis. Since testing can be expensive and time consuming, it is usually reserved for products that meet the following criteria:

- Are from new or questionable suppliers.
- Have been the source of previous complaints.
- Are produced by manufacturers that do not have current good manufacturing practice certification.

The types of tests to be performed will depend on the product and the reason for testing. For most contraceptives (oral contraceptives, intrauterine devices, injectables), visual inspection is usually sufficient unless the contraceptive falls into one of the exception criteria mentioned above. For condoms, however, Level III physical testing is recommended according to indexed sampling plans per ISO 2859-1.

a. Note of Caution on Condom Preshipment Testing

For condoms, WHO recommends that independent lot-by-lot compliance testing indexed by acceptable quality limit (AQL) of the finished product be undertaken using an appropriate sampling plan from ISO 2859-1, before the condoms are accepted for shipment to the purchaser. This is due to the fact that liquid latex, the primary component of condoms, is a natural product whose properties vary from batch to batch depending on the weather, season, and soil quality. This variation in latex results in different performance characteristics for condoms on a lot-by-lot basis.

The condom tests recommended by WHO are identified in *The Male Latex Condom: Specification and Guidelines for Condom Procurement.*[5] These tests include:

- Airburst.
- Water leakage.
- Dimension (width, length, and thickness).
- Package integrity.

[5] First published by WHO in 1989, *The Male Latex Condom: Specification and Guidelines for Condom Procurement* has been periodically updated to provide the latest information both on the capability of the condom industry to manufacture high-quality male latex condoms and on the quality assurance procedures that must be followed to manufacture, procure, and promote condoms.

The purchaser contracts with an independent, qualified testing laboratory to conduct the required tests. The purchaser's decision to accept or reject a lot is based on comparing the test results to the AQL test requirements identified in the condom specifications. If the condom lot fails, the supplier is usually required to replace the lot. If the supplier disputes the test results, then, in many cases, another independent, qualified laboratory mutually agreed upon by both parties is called on to test the condoms, with the results of that test usually binding on both parties. A list of qualified condom testing laboratories is included in *The Male Latex Condom: Specification and Guidelines for Condom Procurement.*

4. Determining the Level of Preshipment Compliance

The purchaser must decide which of the three levels of preshipment compliance tests to perform.

To make this determination, the purchaser must assess each situation, evaluating the performance history of the supplier and the level of risk associated with not conducting appropriate preshipment compliance. The primary risk is that the product quality or quantity may not comply with the contract requirements. While the purchaser still has remedial measures through contract clauses to address noncompliance, the ultimate loss is on the purchaser in terms of delay or nonimplementation of the program.

For RH commodities, it is recommended that the purchaser require Level I (preshipment document review) and Level II (visual inspection) compliance as a starting point. As suppliers establish a track record of problem-free commodity shipments, the purchaser can reserve the right to waive the requirement for Level II preshipment visual inspection for every shipment, and revert to occasional visual inspections performed on a random basis to confirm continued compliance. Level III preshipment compliance is conducted on a selective basis under the special conditions discussed above.

It should be noted that preshipment inspection or testing does not release the supplier from obligations under the contract to replace or compensate for any product found to be nonconforming to the product's technical specifications.

F. Monitoring Commodity Transport

There are four key issues the purchaser must monitor regarding transport of commodities:

- Proper packaging for expected transit conditions.
- Compliance with shipping instructions.
- Compliance with the delivery schedule.
- Proper shipment mode for commodities with special transport requirements.

1. Commodity Packaging

Commodities must be packaged in a way that protects them from potential damage that can be caused by the shipping and handling conditions they are subject to during transport. Inner package and outer packaging requirements to address this risk are included in the technical specifications that the purchaser incorporates into the bidding documents and the contract. The purchaser can monitor compliance with packaging requirements through Level II preshipment visual inspection.

2. Shipping Instructions

Clear shipping instructions ensure that the supplier properly loads and marks the shipping containers. They also identify the specific documentation required for the shipping destination, which helps to prevent delays and customs clearance problems. To help ensure that the supplier complies with shipping requirements, the purchaser should send a copy of the shipping and marking instructions to the supplier at least 30 days prior to shipment. These shipping and marking instructions are taken directly from the contract. They are intended for the supplier's warehouse and shipping personnel, who may not have access to the contract documents. See Exhibit 9-5 in Section H.1 for a sample preshipment instruction form for ocean freight shipments.

3. Delivery Schedule

The delivery schedule established between purchaser and seller is designed to support the program objectives of receiving the correct amount of product at the correct time, having factored in existing stock levels, rate of consumption, available storage, etc. Monitoring the supplier's compliance with the contract delivery schedule has been discussed in Section D of this module.

4. Special Transport Requirements

Some commodities require special shipping conditions to ensure that product integrity is maintained throughout transit to the final destination. For example, some injectable contraceptives should be protected from freezing.

Most RH commodities do not require special storage conditions during transit. The shipping instructions and package markings should, however, contain basic requirements, such as "keep dry" and "protect from exposure to water and extreme heat and extreme cold."

5. Authorization for Shipment

Once a product has passed the visual inspection or testing requirements, and all other requirements are in place (including shipping instructions to the seller), the buyer will issue an Authorization for Shipment, which provides the supplier with written approval to proceed to ship the commodity according to contract requirements. See Exhibit 9-6 in Section H.1 for a sample Authorization for Shipment form.

G. Payment Management

Proper management of contract payments allows the purchaser to exert a certain measure of control in enforcing contract requirements and can help promote a good working relationship with the supplier.

1. Enforcing Contract Requirements

As discussed in Module 8, proper management of contractor payment can help the purchaser enforce contract conditions. For example, through a letter of credit (L/C), the purchaser is able to:

- Enforce quality requirements by requiring the supplier to present documents to the paying bank that provide evidence of successful product inspection and testing.
- Enforce shipping dates, documentation, notification, and marking requirements by requiring evidence of compliance.

The purchaser's leverage under an L/C comes from the fact that if the supplier does not comply with the L/C requirements, the bank will not release the contract payment.

Other methods of payment may be used depending on the value of the transaction and the working relationship established between the purchaser and seller. However, prepayment of the full amount of the contractual obligation to the seller is not recommended, as it minimizes the leverage the purchaser has with the supplier.

2. Promoting a Good Working Relationship

There are several means by which a purchaser can help promote a good working relationship with a supplier. These include open communication, reasonable and appropriate contract performance requirements, and equitable negotiations when required. From the supplier's perspective, one of the paramount concerns is being paid on time once a payment milestone has been completed.

During commodity production, the supplier is expending funds to pay for raw materials, labor, overhead, and other associated costs. Significant expenditures are often required to support production, and if the contract is on a credit basis (e.g., L/C), it is important that the supplier receive payment upon completion of the designated contract payment milestone (such as product delivery) to avoid possible cash flow problems. Prompt and full payment of supplier invoices when the deliverable requirements have been satisfactorily met is one of

the key indicators by which a supplier measures a purchaser's performance, and reliable purchaser performance in this area can help to establish a sound and professional working relationship between purchaser and supplier.

Once the commodity has passed preshipment compliance requirements and is released for shipment to the port of destination, the purchaser assumes responsibility for making arrangements to have the shipment cleared through customs and delivered to the first point of storage, usually a central ministry warehouse. This activity is discussed in Module 10.

H. Reference Material

1. Checklists and Forms

Exhibit 9-1

Establishing Formal Procurement Record Files

Establishing Formal Procurement Record Files

It is important to establish a separate formal procurement record for each procurement transaction. The contents of each procurement record will vary according to the value of the procurement, the type of commodity, and the contract requirements. The following list illustrates the range of documents and information that might be required for a high-value procurement transaction:

- Signed procurement requisition
- Summary description of the procurement process
- Technical specifications
- Cost estimates/budget
- Official approvals
- Prequalification documents
- Bidding/Request for Quotation documents
- Record of any modifications to Request for Quotation documents
- Bidder's list, supplier's list
- Record of advertisements, including dates and entries
- Meeting minutes, including dates, participants, and actions
- Correspondence, dated and signed
- Proposals from suppliers
- Bid/quote evaluation report
- Copy of performance security
- Confirmation of performance security from commercial issuing bank
- Conditional or unconditional award letter
- Contract (signed)
- Schedule for planning and monitoring procurement steps
- Protocols for inspection and testing
- Inspection and test reports, dated and signed
- Shipping and marking instructions
- Copy of shipping documents
- Receiving report
- Copy of inspection report
- Copies of all payment authorizations
- Monitoring form for supplier performance

Exhibit 9-2

Sample Performance Monitoring Checklist

Monitoring Indicator	# Compliant	# Noncompliant	Percent Compliant	Information/Comments
Supplier Deliveries				
Shipments delivered on time in compliance with contract delivery requirements.				
Adherence to Delivery Instructions				
Shipments arrived at port stipulated in contract.				
Correct quantity delivered per the contract.				
Shipments arrived under proper shipping conditions (shipped under proper temperature conditions if required).				
Provision of Documents				
Supplier provided advance copies of documents according to contract terms.				
Shipments arrived with all required documents correctly and completely filled out and signed.				

Monitoring Indicator	# Compliant	# Noncompliant	Percent Compliant	Information/Comments
Packing and Labeling				
Supplier shipped correct package size.				
Shipments with primary packages labeled correctly.				
Shipments with shipping cartons labeled correctly.				
Packaging Materials				
Shipments with external packaging sufficiently rugged to ensure arrival in-country in good condition.				
Technical Specifications				
Products meet all specification requirements.				
Products pass visual inspection.				
Products pass quality assurance testing.				
Shipments with requested quality assurance documentation, such as Certificate of Analysis.				

Monitoring Indicator	# Compliant	# Noncompliant	Percent Compliant	Information/Comments
Product Shelf Life				
Products shipped with a shelf life greater than or equal to that called for in the contract.				
Compliance With Contract Financial Terms				
Invoices that comply with contract pricing terms.				
Shipments correctly insured and shipped according to INCOTERMS stated in the contract.				

Exhibit 9-3

Example Supplier Performance Scorecard

Supplier Name: _____
Contract Number: _____
Month: _____

DELIVERY	Numerator	Denominator	Score (%)
	# of on-time shipments	*Total shipments*	
1. Percentage of shipments delivered on time	88	100	88.0%
	# of full shipments	*Total shipments*	
2. Percentage of shipments fully delivered	88	100	88.0%
	# with adequate documents	*Total shipments*	
3. Percentage of shipments with adequate documents received on time	95	100	95.0%
QUALITY			
	# of products with correct package size and quantity	*Total # of products*	
4. Percentage of products with correct package size and quantity	192	200	96.0%
	# of products undamaged	*Total # of products*	
5. Percentage of products received undamaged due to adequate packaging	194	200	97.0%
	# of products passed	*Total # of products*	
6. Percentage of products that passed quality control testing	198	200	99.0%
	# of products in compliance	*Total # of products*	
7. Percentage of products that comply with shelf-life requirements	188	200	94.0%
CUSTOMER SERVICE			
	# of correct invoices	*Total # of invoices*	
8. Percentage of invoices that comply with contract pricing and terms	97	100	97.0%
SUPPLIER RATING			**94.25%**

Exhibit 9-4

Sample Inspection Order for Condoms

Condom Inspection Order

To: *[insert name of inspection agent/company]*
Date:
Contract Number:
Vendor:
Consignee:

Inspect packing and markings for compliance with Section _____ of the attached Technical Specifications.

Inspection shall be conducted in accordance with ISO 2859-1, Inspection by Attributes.

Inspection level shall be S-3 with an acceptable quality limit of 2.5%:

- For exterior shipping cartons, the lot size shall be the number of exterior shipping cartons, and the sample unit shall be one exterior shipping carton.
- For other levels of packing, the lot size shall be the number of inner boxes, and the sample unit shall be one inner box.

1. Inspect and score for defects as follows:

	Defects*
Contents	Quantity of goods not as specified; packets or strips not as specified
Markings	Omitted; incorrect; illegible; of an improper size, location, sequence, or method of application
Materials	Packaging/packing materials not as specified, missing, damaged, or not serviceable
Workmanship	Shipping cartons inadequately closed and secured; poor application of internal packaging and packing material; distorted inner boxes

** Examination of defects of closure shall be performed on units fully prepared for delivery.*

a. Exterior shipping cartons selected at random from lot proposed for delivery.

b. Inner boxes selected at random from sample shipping cartons.

2. Examine documentation:

Refer to attached shipping instructions and confirm all documents listed are complete.

Confirm that values appearing on Certificates of Analysis for the lot(s) prepared for shipment are within the range mentioned in the product's national regulatory authority dossier and/or specified in the relevant pharmacopoeia per the procurement specification.

3. Provide a written report for approval by the Government of Dharma *[fictitious name]* on packing and markings and documentation prior to release of a clean bill of goods.

4. Unless otherwise specified in writing, the inspection agent is not authorized to sign the "Authorization for Shipment" form.

Exhibit 9-5

Sample Preshipping and Marking Instructions

Sample Preshipping and Marking Instructions

To: _____ *[Insert supplier's name]*
Contract No.: _____
For Shipment(s) to Consignee/Purchaser:

[Insert consignee's name]

Prior to Shipment of Commodities:

1. Contact _____ *[insert name and address of contracted inspection agent/company].*

Upon Receipt of Authorization for Shipment:

2. Assemble packed, marked, inspected, and approved unit packages on a pallet base selected to best utilize the space of a standard *[insert size]*-meter (*[insert size]*-foot) shipping container. Secure load tightly and firmly, without an overhang, using horizontal and vertical strapping. Plastic shrink wrap may be used to stabilize and protect palletized loads.

3. Arrange for a sufficient number of standard *[insert size]*-meter (*[insert size]*-foot) containers to accommodate shipment. Goods may not be consolidated with other freight.

4. Prior to loading, shipping containers must be inspected for cleanliness, safety (free from splinters, snags, dents, or bulges), security (door gaskets, seals, hardware, fittings, etc.), watertight integrity, and overall container seaworthy condition. Contents shall be verified and containers sealed in the presence of an insurance surveyor. A written surveyor's report attesting to the above conditions is required.

5. Load containers to the optimum degree possible without damage to the shipping cartons. Fill all voids by bracing or using fillers to prevent sliding or shifting of cargo. Provide plastic or water-resistant shrouds over the top and sides of the load to protect against damage from condensation that may accumulate on interior container surfaces.

6. Ship in standard *[insert size]*-meter (*[insert size]*-foot) containers via ocean freight on a flag vessel of _____ *[insert country, if applicable]* to

_____ *[insert name and address of consignee, including city and country]*.

7. Commodities must be insured for 110 percent of their total CIF value, covering all risks from warehouse to port of unloading.

8. Do not ship freight "collect." Freight must always be "prepaid."

9. Documentation requirements are as follows:

- Commercial invoice
- Packing list
- Bill of lading
- Certificate of Origin
- Insurance certificate
- Certificate of Analysis
- Clean Report of Findings
- Insurance surveyor's report

10. Commercial invoice must state:

- Name and address of supplier/shipper
- Name and address of consignee
- Invoice number
- Date of invoice
- Letter of credit number
- Contract number
- Place and date of shipment
- Number of shipping cartons
- Weight of each shipping carton
- Number of pallets; number of shipping cartons per pallet
- Number of containers; number of pallets per container
- Lot number(s) and quantities shipped
- Complete description of product, including expiry date
- Unit price of product
- Total FOB value of shipment
- Freight and insurance charges
- Total CIF value of shipment
- Gross weight of shipment
- Country of origin

Marks: _____ *[insert]*
Port of Destination: _____ *[insert]*
Notify Consignee upon Arrival at _____ *[insert telephone number]*

11. Bill of lading must include container number(s), contract number, letter of credit number, and country of origin, in addition to standard bill of lading information requirements.

12. Send to _____ *[insert consignee's name]* via special courier two sets of the following shipping documents (copies are acceptable where originals are required by bank for payment under letter of credit):

- Signed commercial invoice
- Packing list
- Bill of lading
- Certificate of Origin
- Insurance certificate
- Certificate of Analysis
- Clean Report of Findings
- Insurance surveyor's report

13. At least seven (7) days in advance of shipment, advise _____ *[insert consignee's name]* via fax or email of:

- Contract number
- Vessel's name and voyage number
- Booking number
- Container number(s)
- Estimated departure date and estimated date and time of arrival at _____ *[insert port of destination]*
- Bill of lading number
- Quantity of product shipped
- Number of shipping cartons
- Number of containers
- Weight and total value of shipment

Exhibit 9-6

Sample Authorization for Shipment Form

Authorization for Shipment

Attn: _____ [supplier's name]

Ref: Contract Number _____
Letter of Credit Number _____

Authorization for Shipment

Re: _____
[description of goods]

Preshipment inspection and test data have been received and approved by:
_____ [purchaser]

Signature

Signature of this document by the authorized representative indicates that the commodity conforms to Contract Number _____ and is released for shipment.

This certificate does not release supplier from compliance with warranties and other conditions included in this contract.

_____
Authorized Representative

_____
Date

2. Documents

World Health Organization (WHO). *Requirements for the Quality Assurance of Hormonal Contraceptives*. Geneva: WHO; 1995. Available at: http://www.who.int/reproductivehealth/publications/family_planning/HRP_ITT_95_1/en/.

Good Laboratory Practices in Governmental Drug Control Laboratories. In: *WHO Expert Committee on Specifications for Pharmaceutical Preparations. Thirtieth Report.* WHO Technical Report Series No. 748. Geneva: World Health Organization; 1987:20–39.

United States Pharmacopeia Drug Quality and Information Program and collaborators. *Ensuring the Quality of Medicines in Resource-Limited Countries: An Operational Guide.* Rockville, MD: The United States Pharmacopeial Convention; 2007. Available at: http://www.usp.org/worldwide/dqi/resources/technicalReports.

3. Websites

a. Performance Monitoring and Indicators

***Managing and Monitoring Suppliers' Performance: Better Purchasing Guide* (Queensland Government Department of Public Works, 2000)** provides information about simple, practical tools for developing supplier performance monitoring strategies.

http://www.qgm.qld.gov.au/00_downloads/bpg_monitoring.pdf

b. Contract Management

***Contract Management* (United Kingdom Office of Government Commerce)** outlines key considerations in effective contract management.

http://www.ogc.gov.uk/documents/Policy_principles_-_Contract_Management.pdf

Scottish Public Procurement Toolkit (Scottish Government, 2006) is an online source of information regarding procurement and contract management. It offers guidance on procedures and processes, together with templates, and recommends further guidance on particular topics.

http://www.scotland.gov.uk/Publications/2006/11/16102303/0#a10

c. Condom Testing Requirements

***The Male Latex Condom: Specification and Guidelines for Condom Procurement* (WHO/United Nations Population Fund [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 quality assurance 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/

d. Contracting for Services

The World Bank website contains many useful standard, sample, and trial documents for use by borrowers and their implementing agencies in the procurement of goods, works, and consulting services.

World Bank *Standard Bidding Document: Procurement of Non-Consultant Services* (Revised April 2007)

http://web.worldbank.org/WBSITE/EXTERNAL/PROJECTS/PROCUREMENT/0,,contentMDK:21305355~isCURL:Y~menuPK:84284~pagePK:84269~piPK:60001558~theSitePK:84266,00.html

World Bank *Standard Request for Proposals: Selection of Consultants* (Revised March 2002)

http://web.worldbank.org/WBSITE/EXTERNAL/PROJECTS/PROCUREMENT/0,,contentMDK:20061915~isCURL:Y~pagePK:84269~piPK:60001558~theSitePK:84266,00.html

I. Learning Evaluation

1. What are the key objectives of a contract performance monitoring system?
2. What are the key components required to develop a contract performance monitoring system?
3. What are the key activities in establishing formal procurement record files?
4. What are some benefits of establishing formal procurement record files?
5. What four features should a performance indicator have for it to be considered effective?
6. Identify the six common categories for which performance indicators are used to evaluate a supplier's performance.
7. What actions should a purchaser take when a supplier performance problem has been identified?
8. What alternative dispute resolution procedures can a purchaser consider when resolving a dispute with a supplier?
9. What are the three basic levels of preshipment compliance a purchaser can use?
10. For a Level II preshipment visual inspection of product, what product features are inspected to confirm compliance with contract requirements?
11. What are the criteria under which a purchaser should consider conducting a Level III preshipment compliance review?
12. For which contraceptive product does WHO recommend each lot be tested and why?
13. What are four key issues a purchaser should monitor on commodity transport?
14. What are the benefits to the purchaser of properly managing payments to the supplier?

Learning Evaluation Answers

1. The key objectives of a contract performance monitoring system are to:
   - Ensure that all technical specifications and contract requirements are met.
   - Identify performance problems early and correct them.
   - Provide information on a supplier's performance when considering the supplier for future contracts.

   See Section D.

2. The basic components of a performance monitoring system include:
   - Formal procurement records and key performance indicators.
   - Supplier commitment to meet the contractual requirements that form the basis for the performance indicators.
   - Procedures for addressing performance problems and contract disputes.
   - Preshipment compliance plan.
   - Procedures for monitoring commodity transport.

   See Section D.

3. The key activities in establishing formal procurement record files are:
   - Setting up a separate set of procurement files for each procurement.
   - Including all pertinent documents and information.
   - Retaining procurement records for a required length of time.

   See Section D.1.a.

4. The benefits of establishing formal procurement record files include:
   - The procurement record provides essential supporting evidence in the event that it becomes necessary to take legal action against the supplier.
   - The procurement record helps to provide a full audit trail.

- The information contained in the procurement record can be used to help evaluate a supplier's past performance and if additional opportunities to conduct business with the supplier should be considered.

See Section D.1.a.

5. For performance indicators to be effective, they need to be SMART:
   - **S**pecific
   - **M**easurable
   - **A**ttainable
   - **R**elevant
   - **T**ime based

See Section D.1.b.

6. For most high-value RH commodity procurements, performance indicators should be developed that track compliance with the following categories:
   - Technical specifications.
   - Timeliness of deliveries.
   - Labeling and packaging requirements.
   - Shelf-life requirements.
   - Contract terms and conditions.

See Section D.1.b.

7. The purchaser should take the following steps when a performance problem has been identified:
   - Review the procurement record files to identify each party's rights and obligations.
   - Formally notify the supplier that performance is not in compliance with contract requirements. This notification should be in writing and should include the following information:
     - Identification of the problem.
     - Identification of the corrective actions to be taken.

- Identification of the time frame allowed to the supplier to address corrective action.
- Identification of the consequences of failure to correct the performance problem.

See Section D.3.

8. Alternative dispute resolution procedures include:
   - Negotiation.
   - Mediation.
   - Expert appraisal/determination.
   - Arbitration.

   Dispute resolution procedures should be detailed in the contract. They should be listed in order of precedence, and the least severe and least costly method attempted before resorting to more severe methods. See Section D.4.

9. The three basic levels of preshipment compliance are:
   - Level I—Preshipment Document Review.
   - Level II—Visual Inspection of Product.
   - Level III—Laboratory or Physical Testing of Product.

   See Section E.

10. For visual inspection, the purchaser contracts a professional, independent inspection company to randomly select and visually inspect product samples to confirm that the following features comply with contract requirements:
    - Product labeling.
    - Product packaging.
    - Shipping container markings.
    - Product quantity.

    Visual inspection will also reveal any signs of:
    - Product damage or deterioration.

- Package damage.
- Poor workmanship.

See Section E.2.

11. Conducting laboratory or physical testing of a product is done on a selective basis. Since testing can be expensive and time consuming, it is usually reserved for products that meet the following criteria:
    - Are from new or questionable suppliers.
    - Have been the source of previous complaints.
    - Are produced by manufacturers that do not have current good manufacturing practice certification.

    See Section E.3.

12. WHO recommends that independent lot-by-lot compliance testing of the finished product be undertaken using an appropriate sampling plan from ISO 2859-1 before the condoms are accepted for shipment to the purchaser. This is due to the fact that liquid latex, the primary component of condoms, is a natural product whose properties vary from batch to batch depending on the weather, season, and soil quality. This variation in latex results in different performance characteristics for condoms on a lot-by-lot basis. See Section E.3.a.

13. Key issues the purchaser must monitor regarding transport of commodities:
    - Proper packaging for expected transit conditions.
    - Compliance with shipping instructions.
    - Compliance with the delivery schedule.
    - Proper shipment mode for commodities with special transport requirements.

    See Section F.

14. Prompt and full payment of supplier invoices when the deliverable requirements have been satisfactorily met is one of the key indicators by which a supplier measures a purchaser's performance. Reliable purchaser performance in this area can help to establish a sound and professional working relationship between purchaser and supplier. See Section G.2.

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. Percentage of contracts that have a current contract management file.
2. Supplier performance, delivery, and quality are monitored and documented in a supplier scorecard system to evaluate performance.
3. Key contract deliverables are specific, measurable, achievable, relevant, and time based.
4. Policy guidance exists with criteria on when to implement the different levels of preshipment compliance (document review, inspection, and testing).
5. When procuring condoms, the contract includes requirements for testing each lot in accordance with WHO recommendations.
6. The purchaser's dispute resolution policy allows for escalating resolution procedures.
7. Percentage of supplier payments made within the payment period called for in the contract.

K. Glossary and Acronyms

AQL	Acceptable quality limit: The lowest allowable limit of quality in a lot.
AIDS	Acquired Immunodeficiency Syndrome.
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.
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.
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.
Certificate of Analysis	A document certifying quality and composition of goods.
CIF	Cost, insurance, and freight: Title and risk pass to buyer when delivered on board the ship by seller, which pays transportation and insurance costs to destination port.

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.
Consignee	A term used in shipping to describe the party to which something is entrusted (e.g., the "ship-to" party).
Consumption	What individuals and households are able to utilize.
Contract	An agreement entered into by two parties for the execution of a certain activity (e.g., sale and purchase, construction, service provision, etc.).
Contract performance monitoring	Tracking system developed by the purchaser that uses monitoring system key performance indicators to monitor the supplier's compliance with contract requirements.
Criteria	Specific points, standards, qualities, and/or requirements against which something is judged.
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.

Element	One of the ten key operational, broad-based activities in the reproductive health supply process.
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.
FOB	Free on board: The seller fulfills its obligation when the goods pass over the ship's rail at the named port of shipment.
Formal procurement record	File system established by the purchaser for each procurement transaction (contract). Contains all the critical documents and information that are pertinent to the transaction.
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.
Inspection company	Independent, professional organization with staff trained in random sampling and visual inspection procedures. Hired by the purchaser to visit the supplier and inspect a commodity prepared for shipment prior to shipment.
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.
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 which 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).
Marks, markings	An application of numbers, letters, labels, tabs, symbols, or colors for handling or identification during shipment and storage.
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.
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.
Packing list	A schedule showing detailed packing information, including items and totals, number of units or items per box or crate, total number of boxes or crates with individual identification numbers

	provided, shipping marks, total volume of the cargo, weights and dimensions per box or crate, etc.
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.
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.
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 requisition	A document describing what is to be purchased and giving authority to do so.
Quality assurance	See Supplementary Topics, Section H: Product Quality Assurance.

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.
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.
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.
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.