

Session 9:
Prequalification in
Procurement Specifications

Introduction of New Trends and
Implications for Reproductive Health
Commodities



Shift in Financing Reproductive Health Goods

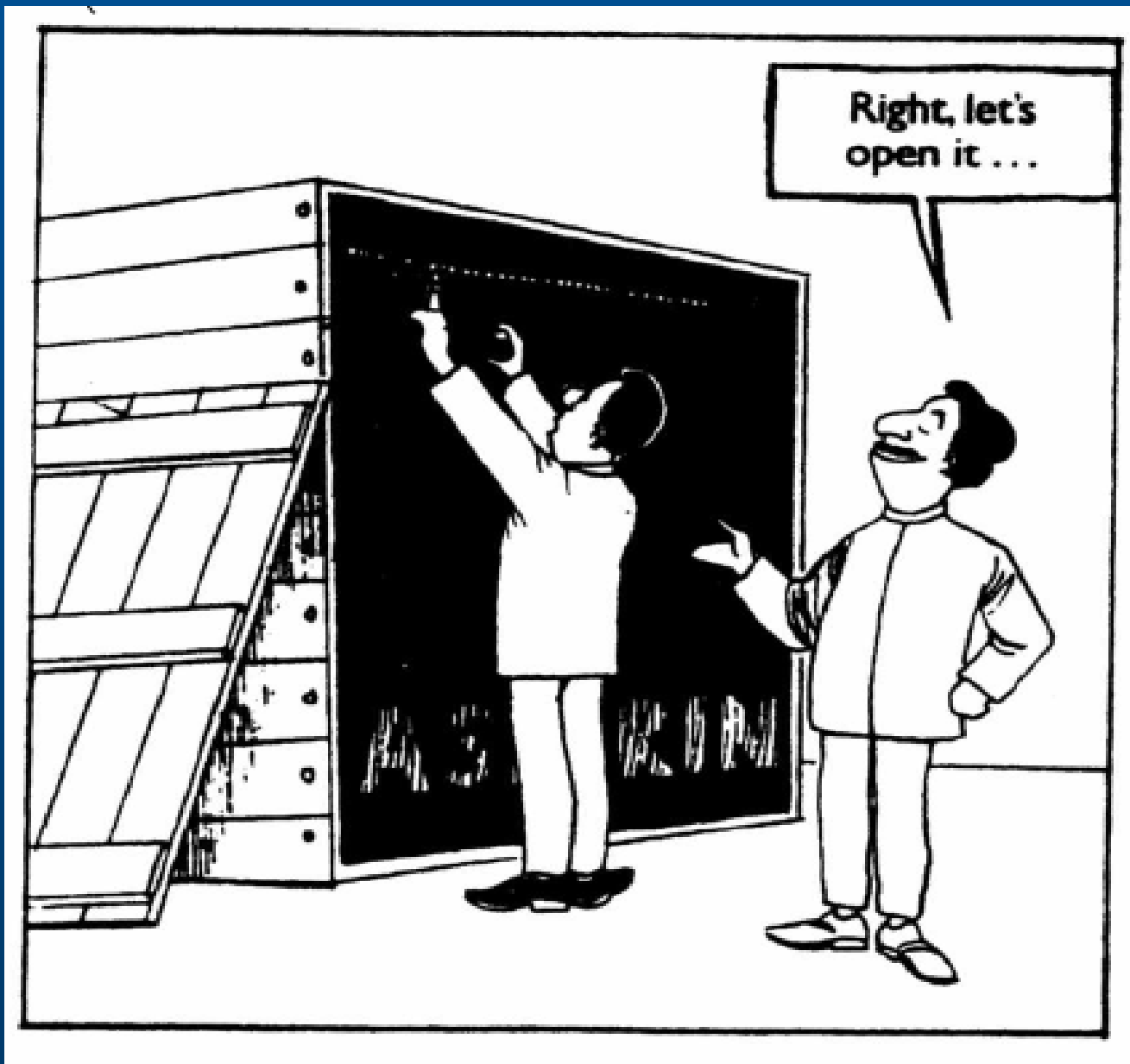
- Reproductive health procurement is shifting to in-country systems
 - Basket funding
 - Sector-wide approaches (SWAps)
- Who will be responsible for ensuring quality products?
 - Country procurement agencies
 - National regulatory authorities (NRAs)
 - Partners in integrated systems

Procurer Specifies Quality

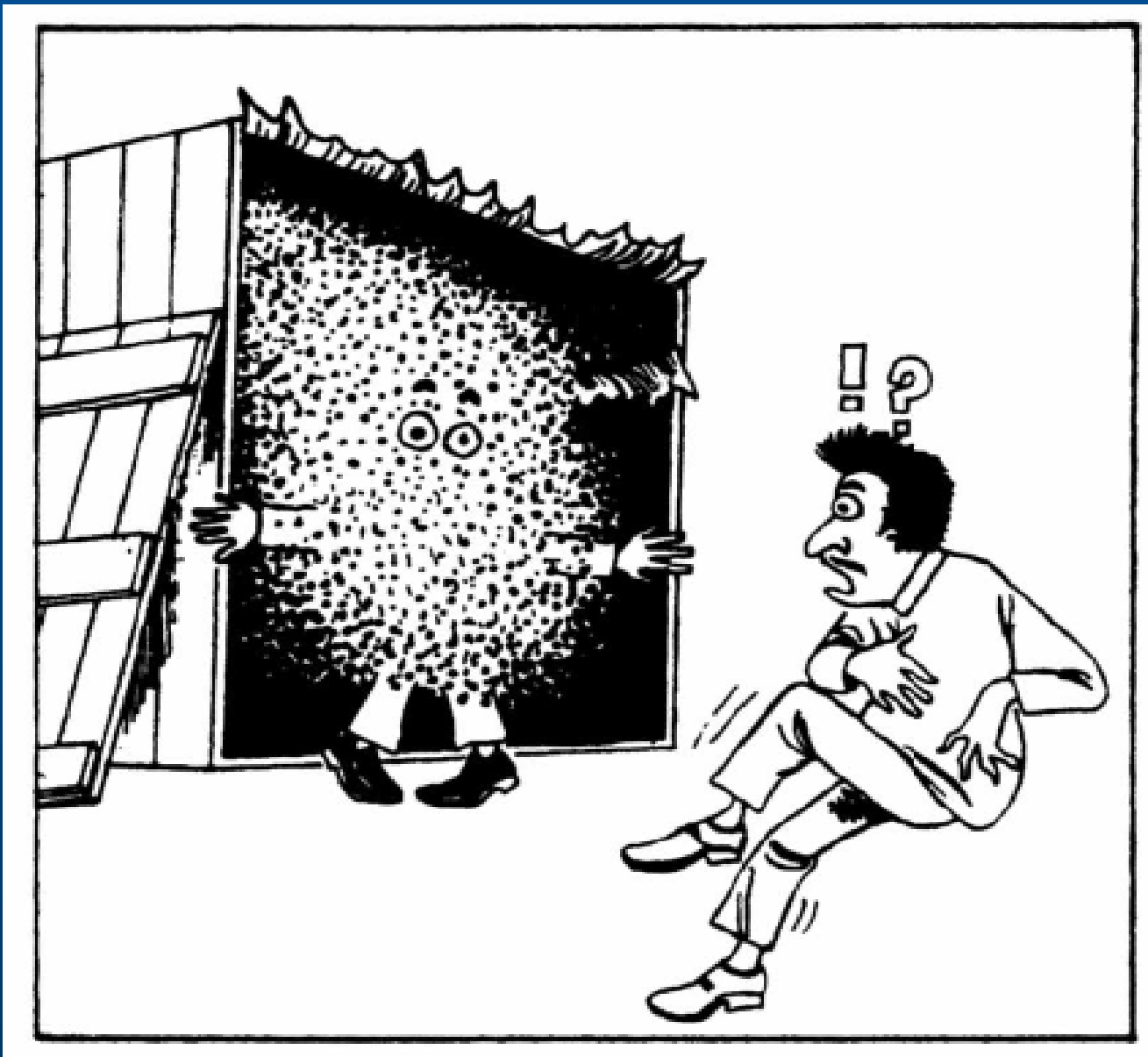
- Articulate quality requirements in specifications:
 - Tender documents
 - Contract documents

Role of Specifications

- Ensure all applicable quality requirements are included:
 - NRA
 - Donor(s)
 - Prequalification
- Specifications are essential in recourse for poor products or conflict
 - Not specified = not enforceable



Managing Drug Supply: The Selection, Procurement, Distribution, and Use of Pharmaceuticals
Management Sciences for Health and WHO
Second Edition, 1997



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Challenges

- Conflicting quality requirements
 - NRA
 - Multiple donors
 - Prequalification
- Establishing quality as a criteria in a cost-driven environment
- Policies regarding open tender processes

Limited Versus Open Tenders

- Limited tenders
 - Only prequalified manufacturers can respond
 - Emphasizes quality over price in bid analysis
- Open tenders
 - All manufacturers can respond
 - May be required by policy in some countries

Solutions

- Consider requiring both WHO and NRA requirements, where appropriate
- Review procurement policies for cost versus quality considerations
- Advocate for limited tenders when quality is at stake
- Quantify and show stakeholders the cost of poor quality to encourage use of the WHO Prequalification Programme

Mock Tender Exercise

- Review excerpts of a tender document
- Identify the mistakes in the specification portion using reference materials provided
- Write corrections on the answer sheet

Incorporating WHO Prequalification Concepts Into a National Tender and Orders

Note: There are two options for this exercise. Option 1 involves reviewing condom specifications and completing a tender exercise. Option 2 is a specifications quiz. Select one of the options according to who the participants are. For example, if participants do not include many procurement staff members and/or English is not widely understood, it may be better to choose the specifications quiz.

List of materials needed:

Option 1 – Tender Example:

- Tender Qualifications Exercise with blank spaces for participants to write answers.
- Tender Qualifications Answer Key for participants to take home and for trainer to have the answers at hand.
- Handout: *The Male Latex Condom*. Chapter Two: Model Specification for Male Latex Condoms. WHO. 2003. Available online at http://www.who.int/reproductive-health/publications/m_condom/who_specification_04.pdf.
- Flipchart.

Option 2 – Specifications Quiz:

- Specifications Quiz with blank spaces for participants to write answers.
- Specifications Quiz Answer Key for participants to take home and for trainer to have the answer at hand.

Instructions to trainer:

Option 1 – Tender Example:

1. Ask participants to sit in groups of approximately five to six people.
2. Pass out the exercise and the handout containing the Model Specification for Male Latex Condoms.
3. Read the instructions written on the participant's exercise and ask if there are any questions.
4. Allow one hour for participants to complete this exercise.
5. When the exercise is finished, inform each group which section of the tender example they will report on, and go through each section of the tender example one section at a time. Repeat for each group until each section has been answered.
6. Ask each group to select one participant to report out with a different participant reporting out during subsequent rounds.
7. Write the answers on the flipchart.
8. Allow 30 minutes for reporting out.
9. After each group reports out, allow all participants to discuss and add any additional answers to the flipchart.
10. After each section, check the answers on the Handout and Trainer's Aid and discuss anything that has not been covered and add notes to the flipchart.
11. Finish the session by asking if there are any further questions.
12. Provide the handout containing the example tender and answers for participants to review and take home.

Option 2 – Specifications Quiz:

13. Hand out the quiz on specifications and ask participants to work together in their groups and answer the six questions.
14. At least one facilitator will sit at each table with a translator if necessary.
15. As a group, discuss each of the six questions.
16. After each question, check the answers on the handout and trainer's aid and discuss anything that has not been covered.
17. Allow an hour for this exercise.
18. Finish the session by asking if there are any further questions.
19. Provide the answer key for participants to review and take home.
20. OPTIONAL: If time is limited, read the six quiz questions to the entire group and take voluntary answers and discuss briefly. Provide handout with suggested answers.

Male Latex Condoms: Tender Qualifications and Specifications Answer Key

Instructions to Participants:

1. The left-hand column lists qualifications and specification details for male latex condoms as may be outlined in an international tender document. There are, however, errors or omissions in the left-hand column.
2. Find the errors and/or omissions and write your answer in the right-hand column.
3. Where the space is completely blank, write what you think should appear there.
4. Use the handout: “Model Specifications for Male Latex Condoms” to review correct specifications for this product.

Specifications and Qualifications of Requested Commodities	Correct Answer or Notation of Omission
QUALIFICATIONS	
<p>Overall Qualifications: Evidence of prequalification of registration by international agencies is required: ISO 9000 PIS listing, or pending PIS application</p>	<p>Overall Qualifications: Evidence of prequalification of registration by international agencies is required: World Health Organization (cGMP certification, PQS listing, or pending PQS application), EU, US Food and Drug Administration, or Japan as applicable. Documentation of certifications from PIC/S ICH countries may be considered in certain conditions, and copies should be included with bid documents.</p>
<p>Product Standards: All products must bear CE markings, UN markings or other indications such as WHO standards, that it has qualified according to internationally recognized standards of the relevant industry. Performance standards must be in accordance with 2074:2002. Certificates of Analysis and Sterility and ISO certificates will be required prior to shipment.</p>	<p>Product Standards: All products must bear CE markings, UN markings or other indications such as WHO standards, indicating that it has qualified according to internationally recognized standards of the relevant industry. Performance standards must be in accordance with 4074:2002. Certificates of Analysis and Sterility and ISO certificates will be required prior to shipment.</p>
<p>Export Experience Distribution Capacity and Capability in Africa and Central American (LAC):</p>	<p>Export Experience Distribution Capacity and Capability in Africa and Central American (LAC): This tender is limited to firms who have substantial experience in international export, import, and distribution of male latex condoms and/or reproductive health (RH) medicines. There is a strong preference for bidders who have distribution capabilities throughout Africa in particular, and also the LAC.</p>

Samples:	Samples: Samples of 200 of each type of product should be sent to the Procurement Officer and Quality Officer. These samples must be sent via courier and must be received by the deadline of the proposal.
Performance Bonds:	Performance Bonds: Although performance bonds are not specifically required at this time, the client, at its discretion, may request a performance bond from the winning bidder(s). This tender is limited to bidders who are able to provide a performance bond if required.
Ability to Register Products in Countries of Export:	Ability to Register Products in Countries of Export: Many of the countries receiving commodities will require manufacturers to register their products in country. Bidders must include a description and timeframe for how and when they will be able to register their products in any or all of the countries.
Product Availability - August, 2008: It is expected that orders for one year's worth of commodities for each country will be placed around July 2008. Orders will likely be released in staggered shipments of approximately one month (although they must be full container loads to the best extent possible).	Product Availability - August, 2008: It is expected that orders for one year's worth of commodities for each country will be placed around July 2008. Orders will likely be released in staggered shipments of approximately four months (although they must be full container loads to the best extent possible).
SPECIFICATIONS	
Materials: <ul style="list-style-type: none"> • The condoms shall not liberate toxic or otherwise harmful substances in amounts that can be irritating, sensitizing, or otherwise harmful to the user of the condom under normal conditions of use. • A suitable dusting powder (e.g., cornstarch, magnesium, and calcium carbonates) should be used to prevent the condoms from sticking together during manufacture and allow them to unroll easily. • Talc or lycopodium spores shall not be used. • Manufacturers should not use excess powder (maximum recommended is 100 mg per condom). 	Materials: <ul style="list-style-type: none"> • The condoms shall be made of natural rubber latex. • The condoms shall not liberate toxic or otherwise harmful substances in amounts that can be irritating, sensitizing, or otherwise harmful to the user of the condom under normal conditions of use. • A suitable dusting powder (e.g., cornstarch, magnesium, and calcium carbonates) should be used to prevent the condoms from sticking together during manufacture and allow them to unroll easily. • Talc or lycopodium spores shall not be used. • Manufacturers should not use excess powder (maximum recommended is 50 mg per condom).

<p>Shelf-life:</p> <ul style="list-style-type: none"> • Condoms shall comply with the performance of this standard throughout the stated shelf-life of the condom. • The manufacturer shall stipulate a shelf-life based on the outcome of stability studies and measured from the date of manufacture. This shelf-life shall be not less than three years and not more than ten years. 	<p>Shelf-life:</p> <ul style="list-style-type: none"> • Condoms shall comply with the performance of this specification throughout the stated shelf-life of the condom. • The manufacturer shall stipulate a shelf-life based on the outcome of stability studies and measured from the date of manufacture. This shelf-life shall be not less than three years and not more than five years.
<p>Design:</p> <ul style="list-style-type: none"> • The condom should have straight and parallel sides, without constrictions, and with a visible shoulder leading up to a reservoir tip. • Shape may be modified in line with normal commercial condom designs. • The open end of the condom shall have a rolled ring of latex, called an integral bead. • The condom should be pink/fuchsia. • The condom shall not give off an unpleasant odor when the package is opened at any time after manufacturer and for the shelf-life of the product. • Appropriate reference samples should be retained by the testing laboratory and can be used to resolve disputes over odor. • The condom should be strawberry fragrancd and flavored. • Size of condom: 53mm width x 170mm length • The condom shall be lubricated. 	<p>Design:</p> <ul style="list-style-type: none"> • The surface of the condoms shall be non-textured throughout. • The condom should have straight and parallel sides, without constrictions, and with a visible shoulder leading up to a reservoir tip. • Shape may be modified in line with normal commercial condom designs. • The open end of the condom shall have a rolled ring of latex, called an integral bead. • The condom should be pink/fuchsia and pigments must be suitable for use in medical devices. • The condom shall not give off an unpleasant odor when the package is opened at any time after manufacturer and for the shelf-life of the product. • Appropriate reference samples should be retained by the testing laboratory and can be used to resolve disputes over odor. • The condom should be strawberry fragrancd and flavored. Fragrances and flavors must be non-toxic and non-irritating and must not degrade the rubber. • Size of condom: 53mm width x 180mm length • The condom shall be lubricated with a quantity of silicone fluid having a viscosity between 200 and 350 centistokes.
<p>Individual package materials and markings:</p> <ul style="list-style-type: none"> • Individual packages shall be square and shall not distort the rolled condom. The package shall be hermetically sealed and shall protect the product from oxygen, 	<p>Individual package materials and markings:</p> <ul style="list-style-type: none"> • Individual packages shall be square and shall not distort the rolled condom. The package shall be hermetically sealed and shall protect the product from oxygen,

<p>ozone, water, vapor, ultraviolet and visible light.</p> <ul style="list-style-type: none"> • The packages should be constructed of a laminate, which includes a layer of suitable impermeable flexible aluminum foil (8 micrometers), and layers of plastic materials suitable for the mechanical protection of the metal foil and for printing and sealing. • The LOT numbers on packages must be printed at the time of packaging. • In addition the following shall apply: <ul style="list-style-type: none"> ○ There shall be no evidence of leakage. ○ The outside surface of the package shall be clean. ○ There shall be no separation of the layers of laminate. ○ If the sealed packages are in strips, the individual packages are separated by perforations or other means that allow the packages to be separated by hand without interfering with the seals. ○ The package must be easy to open without damaging the condom. 	<p>ozone, water, vapor, ultraviolet and visible light.</p> <ul style="list-style-type: none"> • The packages should be constructed of a laminate, which includes a layer of suitable impermeable flexible aluminum foil (8 micrometers), and layers of plastic materials suitable for the mechanical protection of the metal foil and for printing and sealing. • The LOT numbers on packages must be printed at the time of packaging. • In addition the following shall apply: <ul style="list-style-type: none"> ○ There shall be no evidence of leakage. ○ The outside surface of the package shall be clean. ○ There shall be no separation of the layers of laminate. ○ If the sealed packages are in strips, the individual packages are separated by perforations or other means that allow the packages to be separated by hand without interfering with the seals. ○ The package must be easy to open without damaging the condom. • The individual packaging shall be individually marked as follows: <ul style="list-style-type: none"> ○ Manufacturer's name ○ LOT number or LOT identification code (printed at the time of packaging, not pre-printed). ○ Manufacturing date (dip date): Month and year – labeled <i>Manufacturing Date</i> ○ Expiry date: Month and year – labeled <i>Expiry Date</i>
<p>Packaging for Shipment:</p> <ul style="list-style-type: none"> • The inner boxes shall be constructed of board plasticized on its inner surface of sufficient strength and rigidity that the box will retain its shape through every stage of the distribution chain. • The inner boxes will be marked in a legible manner to show the contents and to facilitate identification in case of subsequent query. 	<p>Packaging for Shipment:</p> <ul style="list-style-type: none"> • The inner boxes shall be constructed of board plasticized on its inner surface of sufficient strength and rigidity that the box will retain its shape through every stage of the distribution chain. • The inner boxes will be marked in a legible manner to show the contents and to facilitate identification in case of subsequent query. • The following information shall be

<ul style="list-style-type: none"> • The inner boxes shall be packed into plastic or other waterproof lining bags, which will be placed in three-walled corrugated fiberboard cartons made from weather-resistant fiberboard. • The cartons will be secured by plastic strapping at not less than two positions. • The exterior shipping carton, like the inner box, shall be marked with the information about the contents in a clearly legible manner. The information shall include: <ul style="list-style-type: none"> ○ LOT identification number ○ Month and year of manufacture (including the words <i>Date of Manufacture, Month, Year</i>). The year will be written as a four-digit number and the month as a two-digit number. ○ Month and year of expiry (including the words <i>Expiry Date, Month, Year</i>). The year will be written as a four-digit number and the month as a two-digit number. ○ Name and address of supplier ○ Nominal width ○ Number contained in the carton ○ Instructions for storage and handling • To facilitate monitoring of LOT quality during shipping and storage, all exterior 	<p>included in the inner box market:</p> <ul style="list-style-type: none"> ○ Lot identification number ○ Month and year of manufacture (including the words <i>Date of Manufacture, Month, Year</i>). The year will be written as a four-digit number and the month as a two-digit number. ○ Month and year of expiry (including the words <i>Expiry Date, Month, Year</i>). The year will be written as a four-digit number and the month as a two-digit number. ○ Manufacturer's name and registered address ○ Nominal width, expressed in millimeters ○ Number of condoms in box ○ Instructions for storage <ul style="list-style-type: none"> • The inner boxes shall be packed into plastic or other waterproof lining bags, which will be placed in three-walled corrugated fiberboard cartons made from weather-resistant fiberboard. • The cartons will be secured by plastic strapping at not less than two positions. • The exterior shipping carton, like the inner box, shall be marked with the information about the contents in a clearly legible manner. The information shall include: <ul style="list-style-type: none"> ○ LOT identification number ○ Month and year of manufacture (including the words <i>Date of Manufacture, Month, Year</i>). The year will be written as a four-digit number and the month as a two-digit number. ○ Month and year of expiry (including the words <i>Expiry Date, Month, Year</i>). The year will be written as a four-digit number and the month as a two-digit number. ○ Name and address of supplier ○ Nominal width ○ Number contained in the carton ○ Instructions for storage and handling • To facilitate monitoring of LOT quality during shipping and storage, all exterior
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<p>shipping cartons for each discrete LOT shall be assembled and shipped together.</p> <ul style="list-style-type: none">• Best efforts shall be made to ensure that shipments remain as discrete LOTS and that these LOTS remain intact as far down the distribution system as possible.	<p>shipping cartons for each discrete LOT shall be assembled and shipped together.</p> <ul style="list-style-type: none">• Best efforts shall be made to ensure that shipments remain as discrete LOTS and that these LOTS remain intact as far down the distribution system as possible.
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Prequalification of Condoms: A Cautionary Tale

A government agency in a large country carried out a competitive procurement process to acquire a large quantity of male condoms for one of its programs using the legally required public sector procurement process. An Open International Competitive Bid (ICB) was launched which required no prequalification of potential suppliers.

Supplier's proposals were evaluated and the contract was awarded to the lowest bidder. The selected supplier was not prequalified by any international agency and indeed had not been able to reach the required standard during a prequalification inspection carried out by UNFPA. The condoms were delivered into the country against payment of 80 percent of the suppliers invoice with no pre-shipment inspection and testing.

Post-shipment testing however revealed that the condoms were not of an acceptable quality standard and the entire shipment was destroyed as required by national legislation. The supplier, feeling unfairly-treated, sought payment of the retained 20% of their invoiced costs in the courts of the country and was successful.

Thus the government agency paid the full cost of the condoms and their legal costs and had no product to use in their programs.

It gets worse!

When launching the next ICB for condoms, the government agency sought to exclude the original supplier of poor quality condoms. The supplier again challenged the government in the courts and was successful when the court ruled that their exclusion was unlawful. A decision was made at this stage to engage the services of an international organization which used only prequalified suppliers for the procurement of the condoms.

Suggested Answers for Quiz

1. Name two to three reasons that clear and detailed specifications are important.
 - Ensure the right type of material
 - Ensure the correct quantity
 - Ensure the correct quality
 - Establish accountability and recourse with the supplier
 - Establish appropriate performance with the supplier
 - Ensure that agreements, discussions, and negotiations are captured in writing for reference by all parties
 - Create confidence of users
2. What type of specification requirements might be required by a National Regulatory Agencies (NRA)?
 - WHO certification
 - Registration in-country with the NRA
 - Certificates of Analysis or Sterility confirming that the batch delivered conforms to the specifications and standards
 - Certification of the International Standards Organization (ISO)
3. How are specifications connected to pre-shipment inspections?
 - Pre-shipment inspections confirm that the goods correspond to the items listed on the purchase order.
 - Pre-shipment inspections only inspect goods against the specifications that are included.
 - If other specifications are important, but not included, they will not be acknowledged in the pre-shipment inspection.
4. Identify three or four types of information that would be important in creating a specification for male latex condoms.
 - Design requirements, including color, shape and texture, fragrance, flavor, lubricant, etc.; size; shelf life; performance requirements; packaging requirements; marking requirements; language of markings and instructions; material e.g. natural rubber latex; conformance to specified international standards, such as ISO or WHO.
5. What is the most common specification error that leads to over or under supply of materials?
 - The number of pieces in the unit pack, e.g. box of 100 may be assumed to be the unit size, but is not in all cases.
6. Can a qualification or certification be a part of specification? If so, why would it be important? If not, why not?
 - Yes, qualifying agencies and organizations create minimum performance and material specifications for medical goods. Referencing the standard can add to the specification by allowing it to take the place of fine levels of technical detail. It can also be a detail that assures quality, which is also a specification. A “no” answer is technically not correct, since the questions says “part of”. However, a “no” answer has value when it