



# USAID | DELIVER PROJECT

## Frequently Asked Questions

# Post-Shipment Testing of Condoms



*A customer buys condoms from a drug store in Bangladesh. While many condoms being distributed in-country are made to the highest standards and specifications, or are subjected to rigorous independent pre-shipment testing, some are not.*

**Post-shipment testing is done to ensure that poor quality condoms are not distributed.**

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### **WHAT IS POST-SHIPMENT TESTING OF CONDOMS?**

It is the practice of testing condoms to confirm the quality of products after they arrive in-country, but before the condoms are released for distribution.

### **WHY DO SOME COUNTRIES REQUIRE POST-SHIPMENT TESTING?**

Condom users, service providers, program managers, and regulators know that a wide variety of condoms are being distributed or sold in their country. Condoms have many different manufacturers around the world, and many donors provide condoms. Visual differences among condoms—including the variety of packaging, shapes, colors, sizes, and smells—affect the customers' perception of quality. Some donors, procurement agents, and/or ministries of health use price as the determining factor in condom procurement; they may not always know what product specifications need to be included in procurement protocols. Therefore, questions of product quality, real or imagined, may become an issue. Post-shipment testing (PST) is done to ensure that poor quality condoms are not distributed.

### **HAVE THERE BEEN PROBLEMS WITH PST?**

Yes. In many instances, in-country sampling and testing organization(s) have made mistakes—not drawing a true random sample, not handling or preparing test specimens correctly, not correctly calibrating and maintaining test equipment, not following established testing protocols, not interpreting test results correctly, not using the appropriate standards and specifications, and others. Such errors have resulted in the rejection and destruction of high-quality condoms. This experience has contributed to a lack of trust and partnership among stakeholders. Also, some in-country testing labs do not have the staff, equipment capacity, or space to keep up with the shipment schedule needed to keep programs in full supply. If PST becomes a bottleneck in clearing condoms, there will be stockouts of condoms, and this will create a threat to public health.

### **IS PST VALUABLE AND NEEDED?**

In some cases, USAID and several other donors require manufacturers to meet the latest standards and the most demanding specifications; they also expect the manufacturers to use rigorous independent pre-shipment quality testing at certified labs to ensure that when their product is shipped overseas, it is of the highest quality. PST on these products does almost

nothing to increase confidence in the product, and is not a good use of the limited financial, human, and lab resources. However, not all condoms in distribution within a country are made to the latest standards and specifications, are subjected to rigorous independent pre-shipment testing, come from well-known quality manufacturers, or come through well-established and credible procurement procedures. PST adds the most value in these situations; for example, when condoms are procured locally, or are being imported into the commercial market with little procurement or regulatory oversight. Ministries, regulators, and program managers would benefit from a condom quality risk assessment and from ordering PST only for the condoms that represent the greatest quality risk.

### **DO USAID-PROVIDED CONDOMS NEED PST?**

These condoms should have PST only under unusual circumstances. As indicated earlier, it is poor use of resources and time to require PST for each condom shipment provided by USAID. However, PST may be appropriate *for cause*, if upon receipt of a product, it appears that the risk to quality may have increased because—

- condom cartons have been damaged by water or chemicals
- condom cartons have been damaged through inappropriate handling (punctured by forklift or crushed in storage)
- the condoms have been exposed to extreme conditions (temperatures over 40°C) for a prolonged period of time.

Except under such unusual circumstances, PST for USAID-provided condoms is unnecessary. Furthermore, USAID/Washington does not have the resources to pay for routine PST for its condoms.

### **WHAT IS TESTING “FOR CAUSE”?**

Unlike routine testing, testing for cause is only conducted if there has been a specific complaint or confirmed quality problem with a product. Testing for cause is relatively short term, usually for one or several manufacturing lot(s), or if specific product in a shipping container—it depends on the problem identified. Testing for cause is limited to the products that have the identified problem. If a USAID product is implicated, documentation of the problem should be obtained and forwarded to the USAID mission and USAID/Washington as soon as possible; the document should include the MOH-proposed sampling and testing methodologies and any testing outcomes.

### **HOW IS QUALITY ASSURED?**

Condoms are manufactured according to standards that address safety and performance of the product and, usually, prescribe test methods for quality verification. Male latex condoms procured by USAID, UNFPA, and other international donors are manufactured to comply with ISO 4074 (Male Latex Rubber Condoms—requirements and test methods). Procurement specifications, on the other hand, are based on the ISO 4074 standard; they state the buyer’s requirements and cover all product attributes necessary for buyer acceptance. By detailing the specifications, the buyer determines the characteristics of the product to be manufactured, and states the criteria for product acceptance. Although there could be a variation on certain characteristics, such as a picture or logo on the wrapping material; USAID, UNFPA, and others abide by basic specifications that guarantee quality. For more information, see the following: World Health Organization. 2003. *The male latex condom, specification and guidelines for condom procurement 2003*. Geneva: World Health Organization.

### **ARE THERE POTENTIAL CHALLENGES WITH PST?**

In some countries, PST has been carried out successfully, but there are significant potential problems. Correct product sampling techniques must be used to obtain valid results. It is expensive to equip and train staff for a testing lab that has enough capacity to prevent product delays in the supply chain. Some of the concerns include the retention of qualified staff and equipment calibration. Testing lab accreditation to international standards is demanding; without it donors and manufacturers may not recognize test results as valid for a claim. Additional storage space is needed for any quarantined stocks. There could also be *tie-breaker* testing if PST indicates a defect in a lot of pre-tested donor condoms. To avoid any perception that a *failed* product is unfit for use, USAID may decide to test the product at its own internationally accredited lab. Above all, routine PST could potentially prevent quality products from entering the supply chain and could cause stockouts at service delivery points.

## IF PST IS GOING TO BE DONE, HOW CAN IT BE MADE MORE EFFECTIVE?

There are at least five ways to improve the effectiveness; they can be used in many combinations, depending on the needs of the country.

1. First, good communication with the MOH or other officials can help exclude USAID condoms from routine PST to ensure their delivery to service delivery points is not slowed or prevented. USAID has provided hundreds of millions of dollars of condoms to dozens of countries, and their quality rate has been as high as any donor and more demanding than what is required for access to U.S. consumers. USAID can provide documentation of condom quality specifications for the product they supply.
2. Secondly, outsourcing the testing avoids some problems. If correct random samples are taken and sent by international courier to accredited labs, results can be sent back by email in a few days. Because of economies of scale, it is much less expensive to use these laboratories than trying to maintain an in-country lab. As-needed testing at an international lab can be much more affordable and sustainable than committing to the recurrent costs of establishing and maintaining a local testing lab accredited to international standards.
3. Risk-based analysis is also very effective. This strategy uses a few specific criteria to allocate testing resources where the risk is greatest. As indicated earlier, there is a set of instances for routine PST and a different set of instances for cause-related, episodic PST. Identifying and addressing the greatest risks to programs and consumers for poor quality condoms can reassure the stakeholder community that scarce resources are being used appropriately.
4. An *auditing* strategy can be cost effective. As with financial audits, qualified experts can be called in, unannounced, to do an audit of condom quality. Like the risk-based analysis, a quality audit poses a credible threat of detection to potential bad suppliers. For the possible threat of detection to be effective, all suppliers must be contractually aware of and subject to risk-based analysis and quality auditing.
5. Finally, there must be mechanisms for corrective action when there are quality problems. Purchase contracts should include—
  - terms and conditions that establish quality (specifications and test limits)
  - permit pre- and post-acceptance testing
  - establish a warranty period
  - provide a decision protocol for disposition of product that is deemed unacceptable
  - indicate how disputes will be handled
  - adequately balance the interests of purchaser and manufacturer and program/customer (balancing expectations of quality, rights of the parties, and pricing)
  - allow contract suspension or termination, as needed, etc.

For more information on post-shipment testing, please contact either—

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