Proposed Risk Based Approach to Condom Quality Management
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Proposed Risk Based Approach to Condom Quality

• International procurement agencies (WHO, USAID and UNFPA) have traditionally relied on 100% pre-shipment testing
  • Time consuming
  • Costly
  • Limits flexibility

• Risk based approach to condom quality management
  • Permits reduced pre-shipment testing for manufacturers with proven track record of manufacturing quality product

• Benefits
  • Quicker response times
  • Reduced testing costs
  • Increased flexibility
  • Provides an incentive to manufactures to maintain high quality levels
Testing Options

• Manufactures with proven quality records can be subject to reduced testing by:
  • Test smaller sample sizes from every lot
  • Testing a random selection of lots (skip lot testing)

• Proposed scheme base on Skip Lot Testing to ISO 2859-3:2005
  • Manufacturer with proven quality record that meets defined requirements can reduce the level of testing
  • Reduction in testing limited to about 1 lot out of every 2 (50%) to retain a high level of user protection
  • Concurrent shipment and testing possible for highest quality producers
Manufacturer Qualification Levels

• Approved
  • Entry level for prequalified manufacturers
  • Long term lot acceptance rate maintained above 98%
  • Maintain defined process averages for key properties (burst pressure and volume, freedom from holes and package integrity)

• Qualified
  • Minimum of one year supplying at least 100 lots of product under the prequalification scheme
  • Long term lot acceptance rate of at least 99%
  • Maintain defined process average rates for key properties

• Certified
  • Must have been prequalified for at least 5 years and supplied a minimum of 500 lots
  • Must have achieved and maintained “Qualified” status for a minimum of two years
  • Must achieve and maintain defined process average rates for key properties

• Qualified and Certified manufactures must also have systems for detecting and correcting shifts in quality and have met all delivery dates and volume requirements for last 100 shipments
Pre-shipment Testing Requirements

• Approved manufactures
  • Subject to 100% pre-shipment testing

• Qualified manufacturers
  • Can be considered for skip lot pre-shipment testing (about one lot out of every two in a consignment tested)
  • Manufacturers must also not exceed specified maximum acceptance numbers for the last two lots tested

• Certified manufacturers
  • Accepted for skip lot testing
  • May be considered for concurrent testing
Other Rules for Skip Lot Testing

• If in any consignment any tested lot is rejected then skip lot testing is suspended and all lots must be subjected to testing

• Skip lot testing cannot be reinstated until the specified process averages have been achieved over the last 20 lots tested

• If for any lot in a consignment the maximum specified acceptance number is exceeded then skip lot testing is suspended and all the lots must be subjected to testing

• If skip lot testing is suspended because the maximum specified acceptance number is exceeded, it cannot be resumed until nonconformities in 4 consecutive lots are equal to or less than the maximum acceptance limits
Maintaining Qualification Status

• Qualified and Certified manufacturers must maintain the specified quality and delivery levels

• If requirements are not met then there is automatic demotion to the next category below subject to UNFAP quality review
Reassessment and Inspection

• Approved manufacturers are subject to requalification at least every three years
• Qualified manufacturers are subject to reassessment and inspection at least every 4 years
• Certified manufacturers are subject to reassessment and inspection at least every 5 years
• Earlier requalification may be required if:
  • Recommended by the inspectors at the last inspection
  • There is a downgrading in quality status
  • There are any significant changes in the factory, latex formulation, processes, senior management and/or change in ownership of the factory
Conclusion

• The proposed risk based condom quality management scheme should achieve the following:
  • Reduced levels of testing and associated tests
  • Increased flexibility to respond to changes in demand
  • Improved quality through incentives to maintain and improve quality status
  • Reduce inventory and work in progress
quality
value
choice

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