Risk Analysis
UNICEF – UNFPA – WHO Joint Meeting
September 2017
Dr John Gerofi
Reasons for Update of WHO/UNFPA Specification


• Feedback
  • Manufacturers
  • Testing laboratories
  • Inspectors
  • Partner agencies
  • Other procurement agencies
Document Structure and Layout

• Separate documents for Technical Specification and Prequalification Scheme
  • Prequalification scheme standardised to cover male and female condoms, and IUDs

• Some chapters in Technical Specification removed or merged
  • Technical Specification includes chapter on operation guidance for prequalification of male condom manufacturers
  • Chapter 3 on workmanship and visible defects removed and content merged with performance requirements
  • Section on Guidelines for Procurement removed and will be issued as a separate document
Prequalification

• ISO 13485
  • Accreditation of certification body

• Stability Studies
  • Results of accelerated aging study must be available at the time of submitting an application and a real time study must also be in progress

• Document Submissions
  • Single technical documentation (e.g. STED format)
  • Integrate into Quality Management System
  • Integrate into production plan

• Pre-shipment testing
  • Update table on page 98

• Thickness
  • Current range (0.045 mm to 0.080 mm)
  • Change to ISO 4074:2015
    • average measured thickness within ± 0.010 mm of nominal thickness
  • Measurement of thickness of fully textured condoms
    • Use mass method

• Revise requirements for stability studies (ISO 4074:2015)
  • Improved instructions for real time studies
  • Simplified method for accelerated studies
  • Minimum sample sizes for stability studies (Annex A or Annex B)
  • Studies done on condoms stored in maximum period of time between dipping and foiling, not to exceed two years

• Date of manufacture
  • Date of dipping
  • Date of packaging subject to a maximum storage time of 6 months
Technical Specification – Specification Issues

• Package seal test
  • Individual packages leaking
    • High altitude countries
    • Air freight
  • Improved test in development
    • Dry test specific for leaking lubricant
    • Vacuum level
    • AQL

• Lubricant quantity – nominal quantity range of 350 mg to 600mg within a tolerance of +/- 100mg. If nominal not specified, 450 mg.

• Recommended limit on powder

• Include odour assessment in stability studies
Technical Specification – Packaging changes

• Individual package
  • Square or circular
  • Shall have manufacturer name AND address (can be pre-printed)
  • Lot numbers, MFG and EXP date must be printed at time of packaging and cannot be pre-printed

• Inner boxes
  • Moisture-resistant barrier
  • Plastic bags

• Exterior shipping cartons
  • Durable carton made from weather resistant corrugated fibreboard which can withstand a pressure of more than 1900 kPa
  • Plastic lining bags removed
Product Dossier/Site Master File Issues

• Protein Assay
  • Possible interference from lubricant was discussed
  • Report from ISO TC 157 2016 showed interference is minimal

• Biocompatibility testing
  • Whole condom including lubricant
  • Needed for pigmented condoms
  • Guidelines on when biocompatibility needs to be repeated
  • Results to be interpreted by toxicologist or qualified expert
Product Variations

• Colour, odour, and flavour to be evaluated at prequalification
  • Shelf life verified by accelerated studies, with real time studies in progress
  • Subject to biocompatibility evaluation according to ISO 10993-1
Next Steps

• Drafts to be presented for review as per WHO Expert Committee process

• Working documents to be posted on the WHO website for public comment