Quality Complaints
Introduction

- Types of complaints
  - Product related
    - Pregnancy/infection
    - Breakage
    - Slippage
    - Defects
    - Leaking/empty packages
    - Poor or excessive lubrication
    - Irritation sensitization
  - Commercial
    - Late delivery
    - Missing products
    - Mislabelling
    - Wrong products delivered
Procedures

ISO 13485:2016 requirements

Customer feedback - Clause 7.2.3.c
  Documented arrangements for communicating with customers

Complaint handling - Clause 8.2.2
  Documented procedures for timely complaint handling in accordance with applicable regulatory requirements

Reporting to regulatory authorities – Clause 8.2.3
  Documented procedures for notifying appropriate regulatory authorities of complaints that meet specified reporting criteria of adverse events or issuance of advisory notices

Maintenance of records and sample retention periods – Clause 4.2.5

Corrective and preventative actions – Clauses 8.5.2 and 8.5.3
Clause 8.2.2. Requirements

Define requirements and responsibilities for:

a) receiving and recording information;
b) evaluating information to determine if the feedback constitutes a complaint;
c) investigating complaints;
d) determining the need to report the information to the appropriate regulatory authorities;
e) handling of complaint-related product;
f) determining the need to initiate corrections or corrective actions
Additional Comments re Clause 8.2.2

- Documentation must define minimum requirements and responsibilities
- Justification for not investigating any complaint must be documented
- Any correction or corrective action resulting from the complaint handling process must be documented
- If any third party is deemed to have contributed to the complaint they must be included in the investigation
Reporting to Regulatory Authorities

• In general there is a requirement to report incidents involving death or serious injury associated with medical devices to the appropriate national competent authority (NCA)
• Requirements and procedures for reporting vary depending on NCA
• Documented procedures for determining if reporting to regulatory authorities are required
• Procedures must identify responsibilities for decisions and reporting
• Records of reporting must be maintained
Investigation of Complaints
Handling Returned Samples

- Documented procedures and responsibilities for handling any returned used condoms including disinfection
- An acceptable procedure is described in ISO 29943-1: 2017 Annex H
  - Appropriate protective equipment must be worn (medical grade gloves, laboratory coats, safety gasses, etc)
  - Drop the used condom(s) into a solution containing 4.5% sodium hypochlorite (bleach) for 30 minutes. The recommended volume is 2 L for 30 condoms.
  - Swirl the sample(s) around in the bleach
  - Rinse the condom(s) with cold water
  - Dry between two sheets of absorbent paper for 10 minutes (repeat twice)
  - Finish drying in open air for one hour
  - Apply a suitable powder (e.g. silica or corn starch) to stop the condom sticking
Examination of Returned Condoms (After Disinfection)

- If possible place the condom on a spare dipping mandrel or similar object
- Use magnifying glass and/or microscope if appropriate
- Take photographs of any defects, tears etc.
- Record all information
- Consider if tensile testing is warranted
  - Disinfection may affect tensile strength
  - Original data on tensile strength is unlikely to be available for comparative purposes
- Consider if testing of retained samples is warranted
Testing Retained Samples

- Assess need for re-testing carefully taking into account the nature of the complaint
- Attribute testing (freedom from holes and package integrity testing) may be of limited value
- Focus on burst testing and/or dimensions depending on nature of complaint
- Consider using an independent accredited laboratory if justified
- If appropriate include control condoms in the tests
Discussion and Questions
The United Nations reproductive health and rights agency

Ensuring rights and choices for all

UNFPA