The revised ISO 13528

- Convenors:
  - Marina Patriarca (Istituto Superiore di Sanità, Italy)
  - Dragan Nikolic  
    (Directorate of Measures and Precious Metals, Serbia)

- Objectives: Consider the implications of the revised ISO 13528 standard for PT/EQA Providers
Participants

- Participants are:
  - Accreditation bodies 6 (12 %)
  - PT providers 37 (74 %)
  - Other 7 (14 %)
    - NMI 3
    - Laboratories 3
    - University 1
- Total 50

1. Will the revised standard create issues for you as a provider in the organisation of your PT/EQA schemes?

- New symbols:
  - will require changes in procedures
  - not big change
  - not yet harmonized with ISO/IEC 17043
- For small number of participants z'-score may not be acceptable
- More flexibility in statistical approaches may cause lack of harmonisation between PTP
- Customers may find it difficult to handle the information
How are the ABs going to apply the standard across EU

Flags for the measurement uncertainty should be optional

2. Does the revised standard address those problems encountered with the previous version?

- We have not seen the new standard
- There were not many problems with current standard
- Yes, for given more flexibility for homogeneity/stability testing
- Yes, covering requirement for the uncertainty of analytical method
- Yes, relaxing requirement for using z’- score
- Yes, more flexibility for statistical methods
- Yes, statistical design clearly linked to PT objectives
- Yes, the standard covers other sectors, e.g. microbiology
- It is easy to read, more examples included
- Less strict, allow PTP to try new things
- Flags for laboratory uncertainty
  - Since many labs have a problem with MU

3. Do you foresee a need for guidance on how to implement the revised standard?
- Not much
- Some short guidance to point out the changes
- Some guidance for ABs!, to make assessment comparable
- Additional guidance for microbiology
4. Is the revised standard now applicable to all types of PT/EQA schemes?

- It covers most PT, but
- No provision for sampling PT (e.g. homogeneity/stability)
- Cohen’s k not covered, new work item