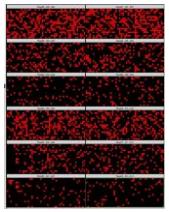
CCQM NAWG

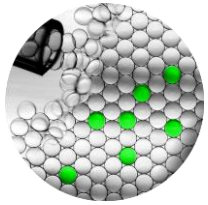
“Elevator Pitch”

CCQM Strategy Workshop: BIPM April 26, 2017

Major Achievements:

- P & K Study series in nucleic acid quantitation providing support for participant services
  - Substantial improvement in NMI inter-laboratory precision in nucleic acid quantitation (from an essentially zero base) and elucidated uncertainty budgets (including published guidance) for NA quantitation by qPCR
  - Significant growth in NMI/DI NA measurement service provision
  - First NA measurement based CMCs
- World leading expertise developed in NA copy enumeration by dPCR
  - Framework for NA measurement SI traceability based - Clarification with CCU / 9th SI brochure unit 1
  - Influence on technology manufacturers



Major Challenges (Ongoing…)

- Challenges & opportunities with increased NAWG participation
  - diverse range and maturity of service provision
- Very broad claims required to cover range of services
  - genome /matrix combination “infinite”
- Largely “competence based” requirements – “NA quantification….”
  - Need to clearly define extent of “measurement space” demonstrated by each study (e.g. matrix type, dynamic range, NA size constraints)
  - Design of study – very challenging careful consideration of study design to maximise range of service provision supported
- Rapidity of technological change

What's New?

- Criteria for prioritisation of study planning Based on NMI/DI NAWG member survey
- Principal stakeholder requirements for measurement services:
  - Genetic Diagnostics , Food & Feed Quality / Regulatory support & Pathogen & Infectious Disease Detection
- Dominant measurement services:
  - RM certification, Calibration services for value assignment,
- Service NA measurement requirements
  - Current - NA quantification (DNA, mRNA expression)
  - Future trend - sequence, miRNA, epigenetics, gene editing/synthetic biology

NAWG CONFIDENCE IN SCOPE & CLARITY OF NA MEASUREMENT SPACE - "MATURITY"

Comparisons?

- Cannot realistically carry out more than 1- 2 comparisons/year - resource intensive.
  - Maximium 1 Pilot & 1 Key commenced per year
  - Decreasing to 1 relating to measurement complexity
- NAWG group will continue to develop and refine study strategy based on evolving services and stakeholder requirements
  - Planning horizon 2-3 years
- No repeat studies planned
- Small number of studies but very focused in well mapped “measurement space” – supporting range of services