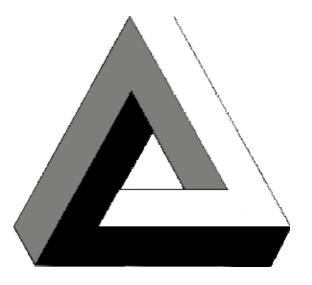
Quality Assurance – A paradoxon ?

Institut of Criminalistics – 60 anniversary

Prague, October 10th 2018





Dr. Michael Bovens

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Relevant Documents



- Lessons learned from Assessments
 - Assessor and being assessed





Relevant Standards:





- General requirements for the competence of testing and calibration laboratories
- ISO 17020:2012
 - Conformity assessment Requirements for the operation of various types of bodies performing inspection
- ILAC G19:08/2014
 - Modules in a Forensic Science Process
 - Multilateral agreement and mutual acknowledgment of documents between European-co-operation for Accreditation (EA), International Accreditation Forum (IAF) and International Laboratory Accreditation Cooperation (ILAC)
- ISO/IEC 17043:2010
 - Conformity assessment -- General requirements for proficiency testing



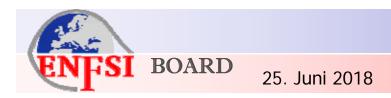
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ilac

Relevant Standards:



- TC 272 ISO 21043 : Forensic Sciences
 - since 2015 under construction
 - ca. 2022 planned implementation
 - **5** separate and individual Sub-documents
 - already acknowledged by EN
 - BUT: Accreditation ≠ Certification ≠ Technical Standard
 - 1 standard in close relation to Forensics on Consumables (WG3)
 - ISO WD 20964 Specification for consumables used in the forensic process: Requirements for product manufacturing and kit assembly



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TC 272 ISO 21043 Part 1 - 5 : Forensic Sciences



- Part 1: Terms and definitions (ISO 21043-1:2017)
- Part 2: Recognition, recording, recovering, transport and storage of material (ISO 21043-2)
- Part 3: Analysis and examination of material (ISO WD 21043-3)
 - Convenor: The Netherlands
- Part 4: Interpretation (ISO WD 21043-4)
 - Convenor: The Netherlands
- Part 5: Reporting (ISO WD 21043-5)
 - Convenor: Australia



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Paradoxon of Quality Assurance



- What I do, I do not recognize (timely/consequences). What I intend to do, I do not, but what I hate, this I do
- Any measure which does not improve the process in effectivity or efficiency is not a quality improvement
 - Efficiency: Do the things right; Speed up, prevent doubling actions (administration, multiple control mechanisms for the same thing)
 - Effectivity: Do the right things; Prevent mistakes, Fit for purpose; Meet customers need
- What 'goes up' by the taken measure /improvement?

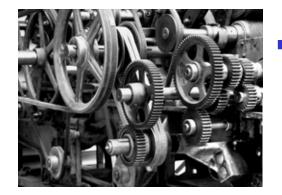




Challenges and Chances in Quality Assurance



- Challenge: QA/Accreditation became a 'business'
 - requirement of increased documentation
 - overlapping requirements
 - like personal certification additional to lab accreditation
 - all-over chain of evidence



Steering or steered ?



Challenges and Chances in Quality Assurance

- Chance: SIMPLICITY
 - reduction to the key-factors is not at all 'quick and dirty'
 - Ockhams Razor Blade

SIMPLICITY IS Complexity well done





- Size of documents
 - if it's not read, it's dead
 - trained staff or monkey?



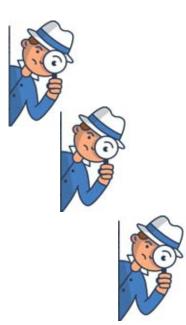
Validation

- qualitatitve / quantitative / comparative
- Validation Plan / Data Documentation / Validation Report
- Great inconsistency between department in the same (big) organisation

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Controlling

- if the control is controlled, something goes really wrong!
- Trust means courage and responsibility on both sides
 - Degrees of delegation
- Mistakes will happen!
 - Adequate reaction (nescience, ignorance, intension, attitude?)





- Go straight
 - praise of multi-tasking is refuted
 - question administrative/decision making steps
- Product development and introduction
 - include customer/practitioner from the beginning





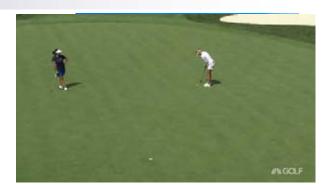


- Assessors and 'False Prophets'
 - Non-conformities where is it written?









RESERVE!





- Peak Performance Power of endurance Breaks
- Releasing the own stocks / outsourcing is managerial short term thinking
 - goods to the street'
 - is recuperation a private matter
- Lack of reserve is a risk! → ISO 17025:2017 Chap.
 8.5.













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Happy Bin