The ISO 17043 from the perspective of Laboratory Medicine:
Do we need revision?

Result from Questionnaire + Discussion

Introduction

2018: EQALM meeting Zagreb

ISO 17043	Moderator: Stephanie Albarede	
15.10 – 15.30	A need for revision of the ISO 17043 standard	Michael Noble

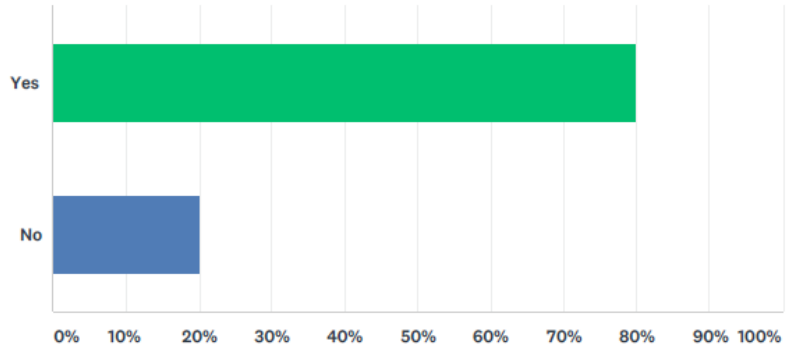
2019: Questionnaire (1)

TFG ISO 17043

It is expected that in the near future (2020) ISO-CASCO will start the revision process of the ISO 17043 standard. The EQALM board is already in contact with ISO to become an official recognised partner in this process. To be prepared for this revision we would like to start a Task-and Finishing Group on ISO 17043. The purpose of this group is to prepare input for the revision of the standard. This group will exist during this revision process.

Q6 My EQA organisation is interested to participate in this TFG:

Answered: 15 Skipped: 5



ANSWER CHOICES	RESPONSES	
Yes	80.00%	12
No	20.00%	3
TOTAL		15

Board decided to establish this TFG.
Chair : Stpehanie Albarede
Co-chair : Michale Noble

2019: Questionnaire (2)

EQALM Task anf Finishing Group
ISO/IEC 17043

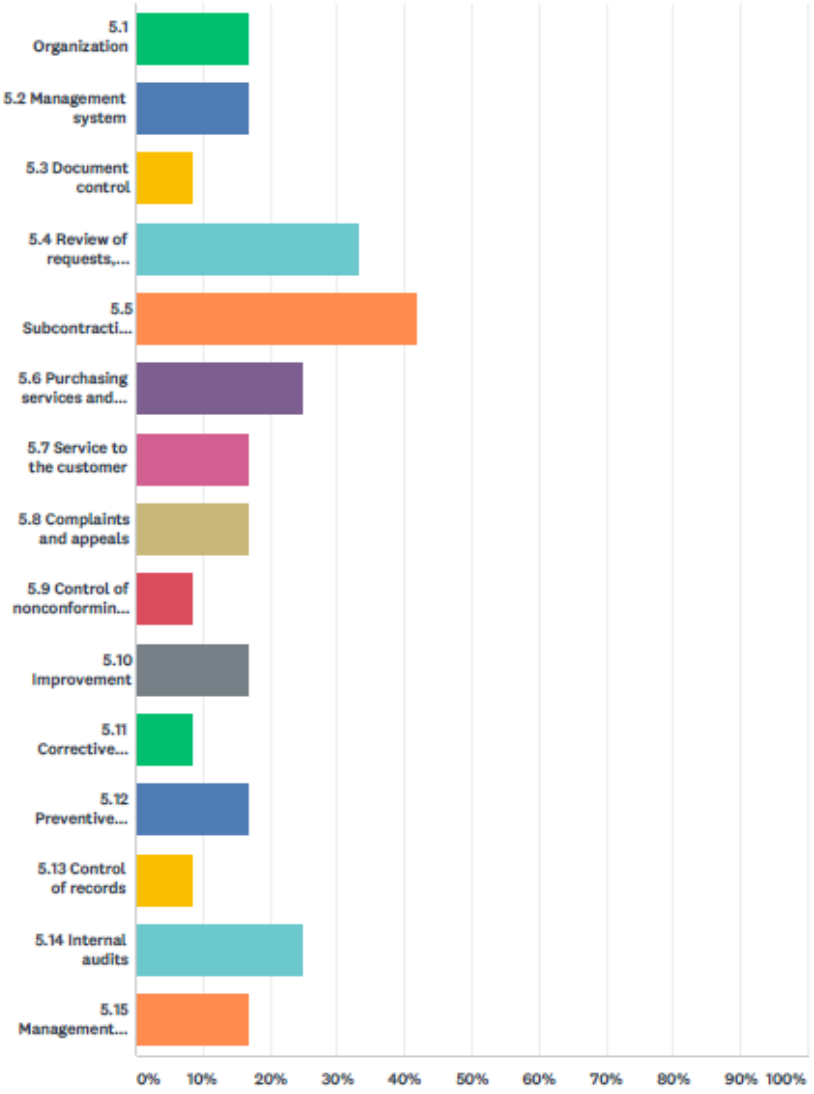
1. As announced by the EQALM board in Zagreb, it was decided to start a mirror group for the revision of the new standard 17043 "Conformity assessment - General requirements for proficiency testing". This mirror group will act within EQALM as a Task and Finish Groups which will be chaired by Stéphanie Albarède and co-chaired by Michael Noble.
In order to optimize the discussions of this TFG, EQALM is seeking the opinions of interested EQA providers about this standard. This survey focusses on your organization's opinions and experiences with this standard.
The responses to this survey will be discussed in Ljubljana. All responses will be presented as anonymous and will NOT be linked to you or your organization.
The information will be used to assist EQALM to represent organizations who provide EQA services for Medical Laboratories.

Friday 11 October: 17 Responses

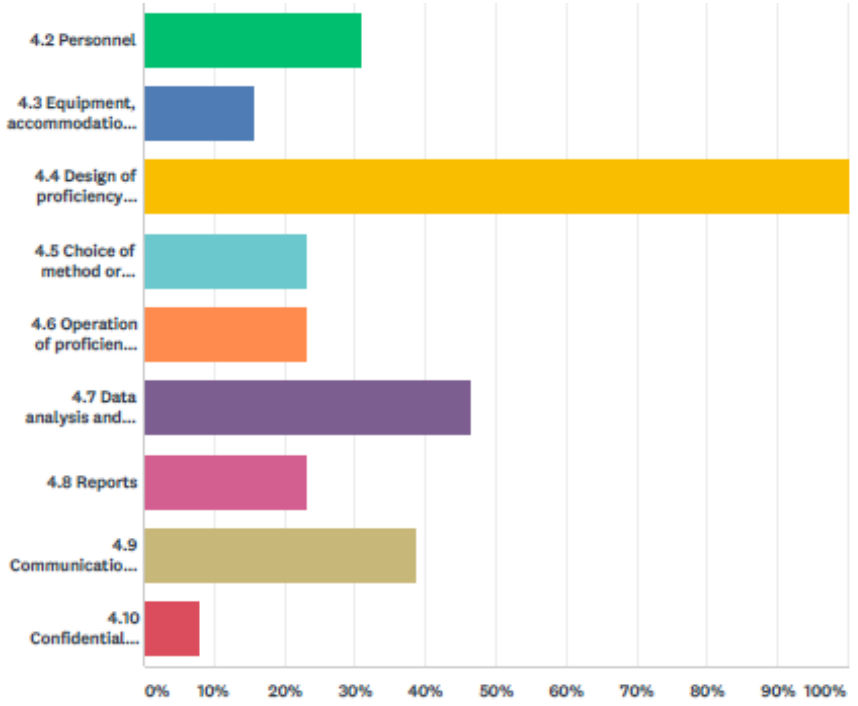
2006 - 2015

ANSWER CHOICES	RESPONSES	
Yes	70.59%	12
Not yet but we are considering	5.88%	1
Not yet but we are actively working towards	23.53%	4

Management Requirements



Technical Requirements

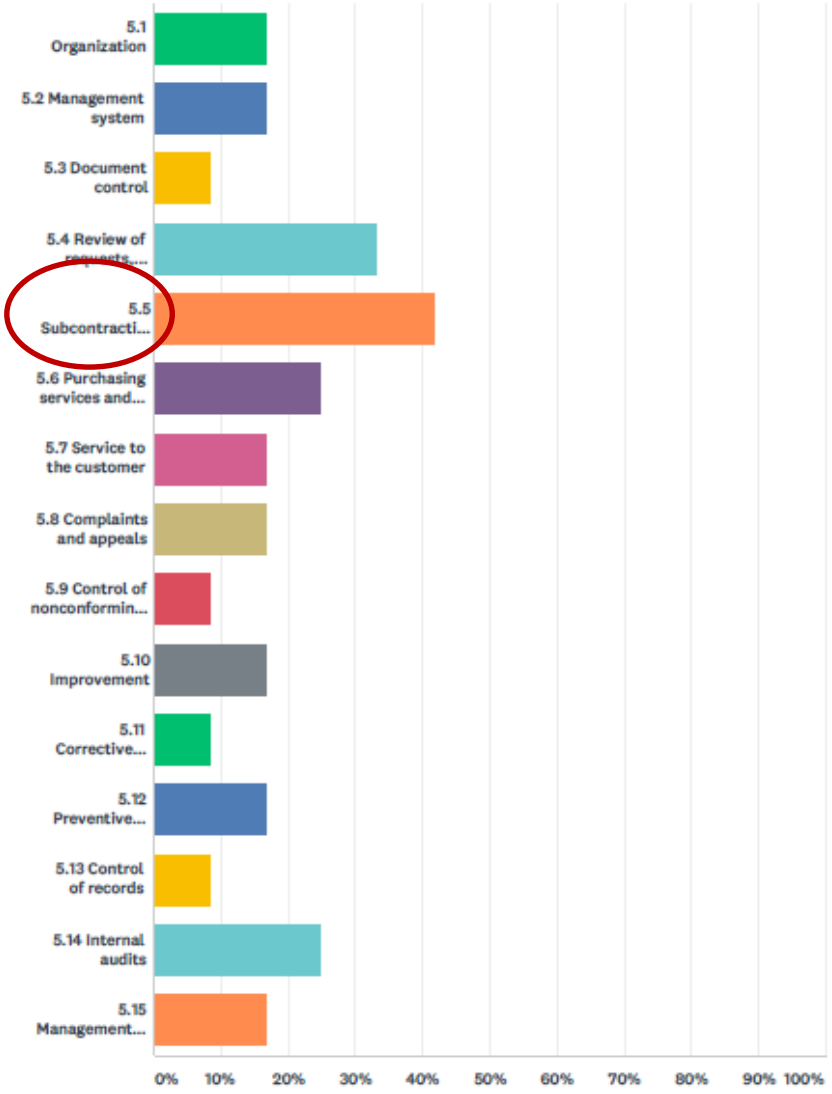


Observation:

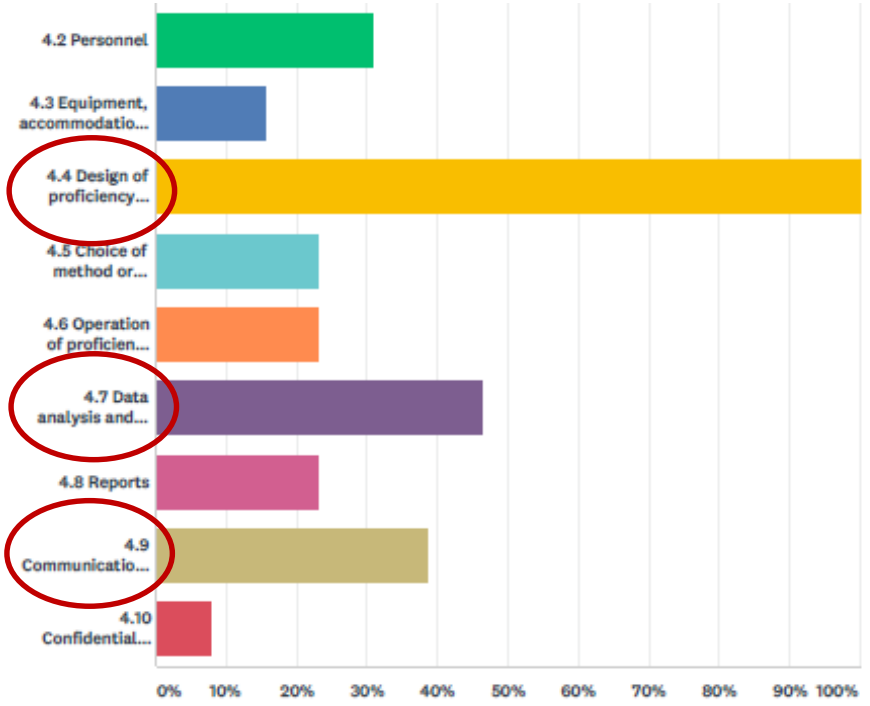
1) All elements of the norm are mentioned!
2) The majority mentioned required revision for technical requirements

Comments?

Management Requirements



Technical Requirements



Design of proficiency testing schemes

1	Misunderstanding of the concept of sub-contractor and misunderstanding of some requested needs for the entity's preparation, such as specification to the subcontractor, stability
2	4.4.1.1. Should the processes with direct affect to the quality of the PTS identified in a separate document? 4.4.1.3. c) Who must be identified as a subcontractor? (eg. control sample supplier, courier company, hazardous waste removal/disposal) g) is it compulsory to give the range of values of each analyte in a PTS? (It is written ranges of values OR characteristics) Are the range of values determined by analyte in the Detail of Accreditation? j) Curious about other EQA provider's precaution's regarding preventing collusion between participants or falsification of results? 4.4.3. During period of preparation to the accreditation it caused quite a lot of problems to get the homogeneity and stability documents from the PT item suppliers.
6	4.4.1: There is a discrepancy between this point, which applies to pre-startup plans, and that one is most likely to apply for accreditation after a time when the EQA program has been in operation. Then it may be difficult to document the plan.
7	We have longstanding discussions with our accredatation body about homogeneity and stability testing on: - each parameter? - frequency - control on homogeneity and stability testing by our sample producers
8	defining homogeneity testing procedure and criteria, random sampling

Is the standard fit-for-purpose in laboratory medicine?
e.g. Do we need special requirements for homogeneity and stability testing?

Data analysis

1	Misunderstanding of the need to secure the means of calculating (in Excel). The concept of the need to use valid evaluation methods can be interpreted differently.
2	4.7.1. Exact definition of validation/verification of data processing software?
5	4.7.1.1: It's difficult to know what is required here regarding validation.

4.7 Data analysis and evaluation of proficiency testing scheme results

4.7.1 Data analysis and records

4.7.1.1 All data processing equipment and software shall be validated in accordance with procedures before being brought into use. Computer system maintenance shall include a back-up process and system recovery plan. The results of such maintenance and operational checks shall be recorded.

4.7.1.2 Results received from participants shall be recorded and analysed by appropriate methods. Procedures shall be established and implemented to check the validity of data entry, data transfer, statistical analysis, and reporting.

Software validation: always necessary?

Data entry validation: what about electronic data entry by participants?

Communication with participants

5	• Totally is missing the requirement to publish EQA plan at the web page. Many EQA providers are operating in stealth mode – nobody has a chance to know anything about them, about their programme, schemes, criteria, prices etc. There should be added a chapter explicitly defining the minimal amount of information that must be publicly available (at provider's web page, without need to register, log in, or pay). These information must be available to everybody, not only to "customers" or "participants".

Comments?

Subcontracting

1	Misunderstanding of the concept of subcontractor: collaboration with another centre, but also a simple vendor of entities
2	Implementation of this requirement is complicated because we belong to a public entity with operating rules that prevent its application. We are in the process of sensitizing the board to this fact.
3	5.5.3. Who can be considered a sub-contractor? (point 4.4.1.1.) Is it enough to mention in a document for the participants that in a spec. field we apply subcontractors or should they be specified by name?
4	How to evaluate and identify subcontractors
6	It must be specified what a subcontracter is
7	- Difference between "Subcontracting services" and "Purshasing services and supplies" is not clear.
8	We had discussion with our accreditation body about the fact whether supplying sample material from an external producer is subcontracting or purchasing services (paragraph 5.6). We experienced that ther could be also differences in opninion between auditors.

Subcontracting or purchasing services: What is the difference?

Next steps:

- The questionnaire will be open till the end of October.
  Link: https://fr.surveymonkey.com/r/BMFKSZ7

- Short meeting after the General Assembly

- Set-up of a working plan to accomplish a recommendation on behalf of EQALM for the revision of ISO 17043