

Survey on the Accreditation of EQA Schemes in Laboratory Medicine

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Survey design

- On-line Survey distributed by e-mail link to all EQALM member organisations in August
- Survey software used - Survey monkey

Aim

- to audit accreditation status in 2011 against 2005 data
- To ascertain extend of implementation of ISO 17043 amongst members

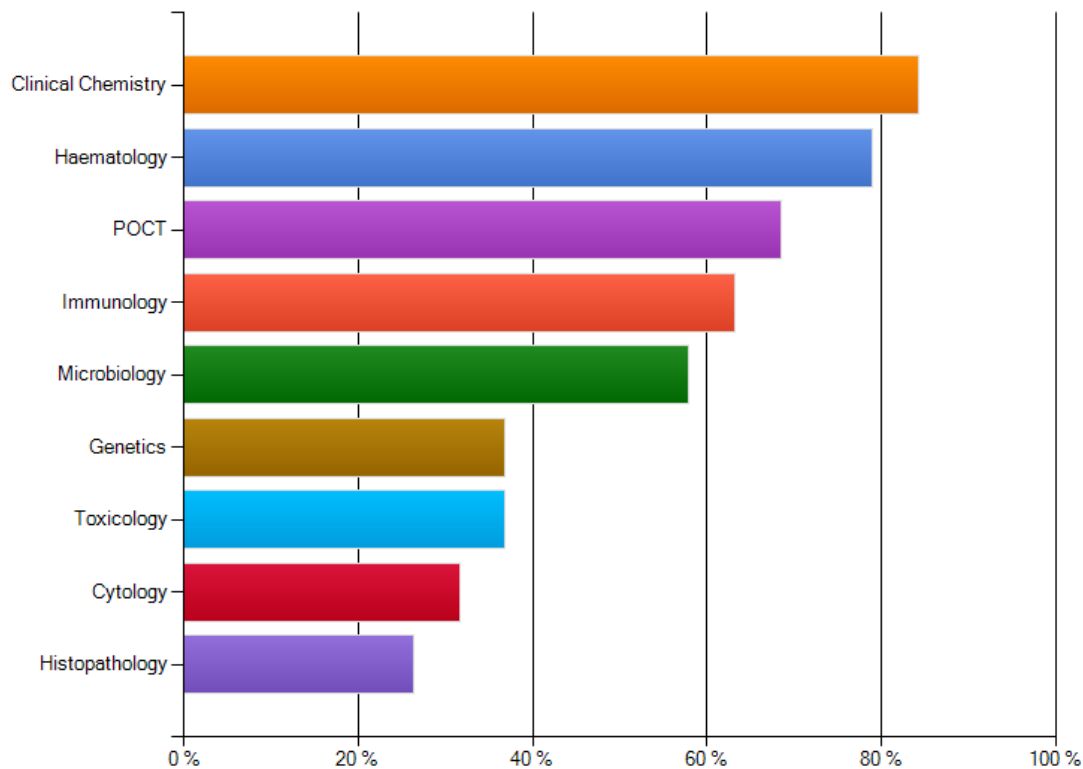
Q.21 Country of
Organisation

17 Countries
represented

Country	no of Responses
Austria	1
Canada	1
Croatia	1
Czech Republic	1
France	1
Germany	2
Hungary	1
Ireland	1
Italy	1
Netherlands	1
Norway	1
Oman	1
RUS	1
Spain	1
Switzerland	2
UK	4
Unknown	1
Total	22

Q.20

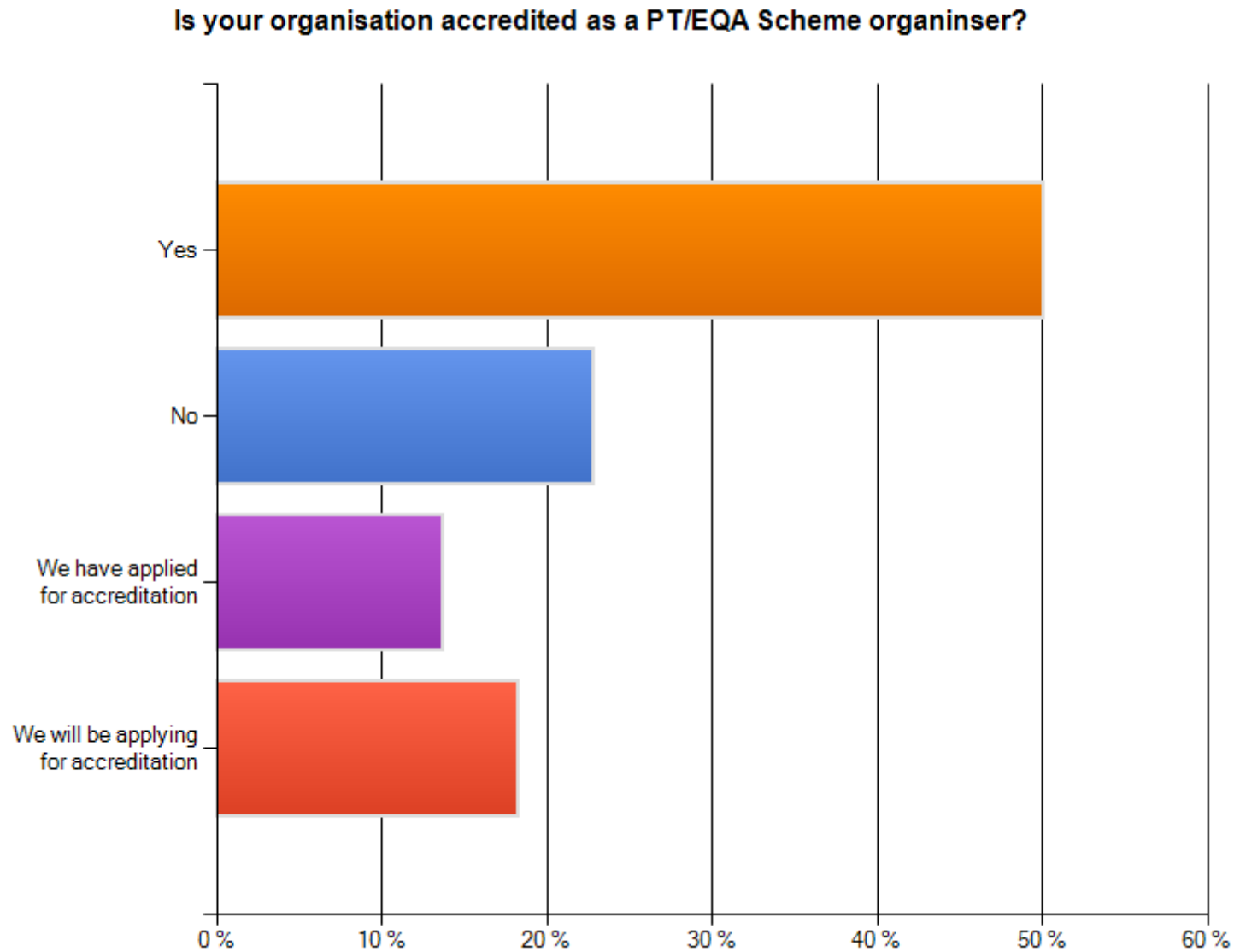
Please provide details of the technical field(s) in which you offer EQA Schemes ?



Page 5, Q1. Please provide details of the technical field(s) in which you offer EQA Schemes


- 1 haematinics
- 2 Legal medicine, Instruments: Sterilisation, Spectrophotometry Education: Preanalytic
- 3 We only provide 4 schemes: General Clinical Chemistry; FBC; Blood Cell Morphology; HbA1c (inc. POCT).
- 4 Coagulation
- 5 Drug monitoring

Q.1



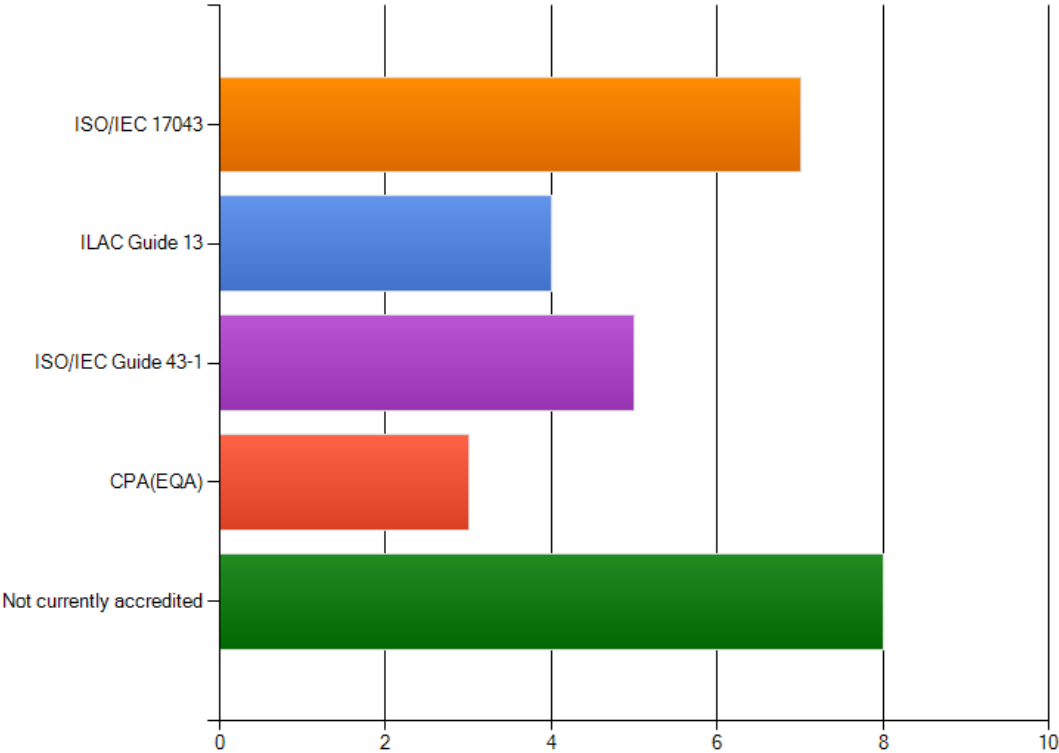
In 2005 only 28% were accredited

Q.2

2. Are you accredited for all or some of your Schemes? 				
	All	Majority	Some	None
Chemistry	43.8% (7)	18.8% (3)	0.0% (0)	18.8% (3)
Haematology	56.3% (9)	18.8% (3)	0.0% (0)	6.3% (1)
Histology	27.3% (3)	0.0% (0)	0.0% (0)	27.3% (3)
Immunology	40.0% (6)	20.0% (3)	0.0% (0)	13.3% (2)
Genetics	15.4% (2)	23.1% (3)	7.7% (1)	15.4% (2)
Microbiology	14.3% (2)	21.4% (3)	0.0% (0)	28.6% (4)
POCT	46.2% (6)	7.7% (1)	0.0% (0)	23.1% (3)

Q.3

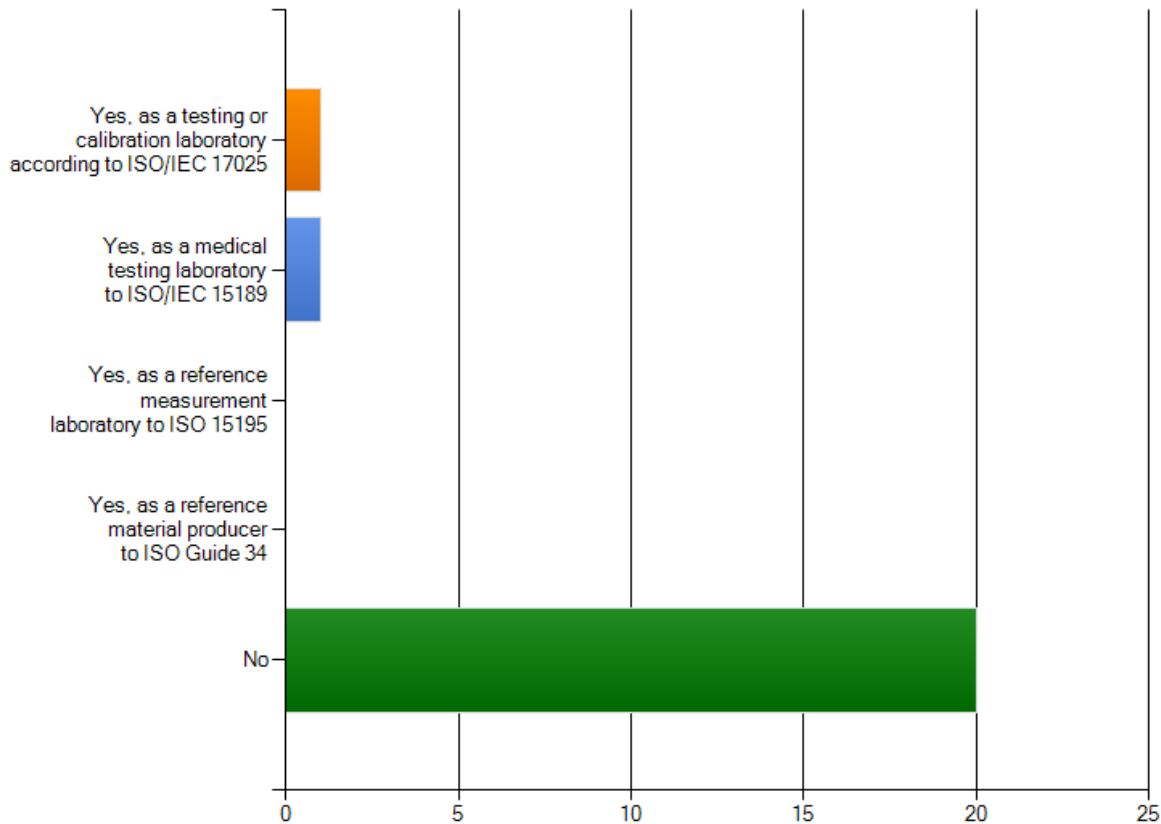
Which standard(s)/guide(s)is your organisation currently accredited to?



	Which standard(s)/guide(s)is your organisation currently accredited to?
	ISO/IEC 17043
Yes	57.1% (4)
No	0.0% (0)
We have applied for accreditation	28.6% (2)
We will be applying for accreditation	14.3% (1)
Other (please specify)	1 reply
answered question	7

Q.6

Does your organisation hold another accreditation ?



In 2005

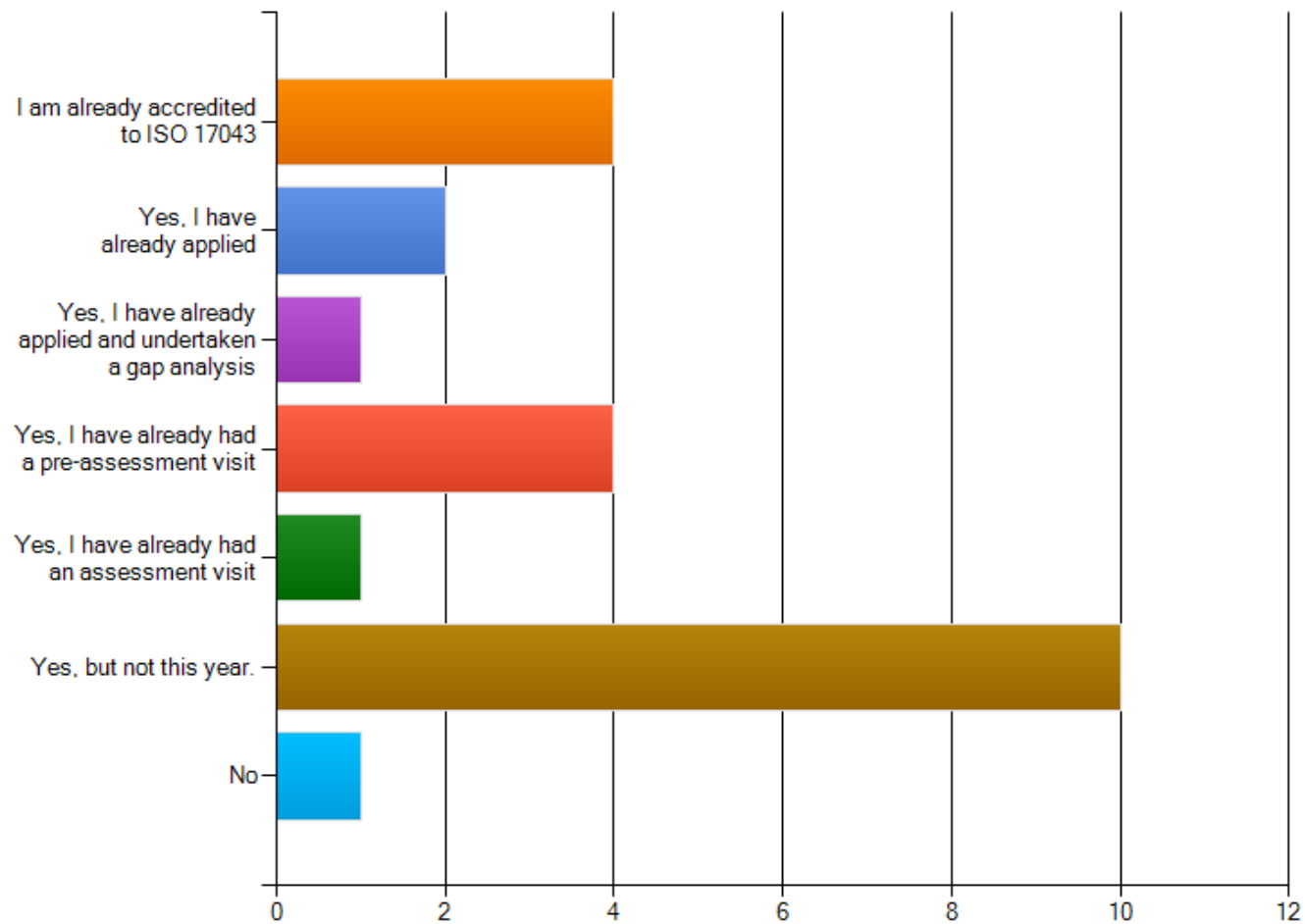
20% accredited to ISO 17025
or 15189

Page 2, Q1. Does your organisation hold another accreditation ?

1	ISO 17020
2	see 3 ISO 14136 / ISO 17020
3	ISO 15195 and EN 14136
4	According to CPA Accreditation for Laboratory Medicine and not ISO 15189
5	We have not decided yet

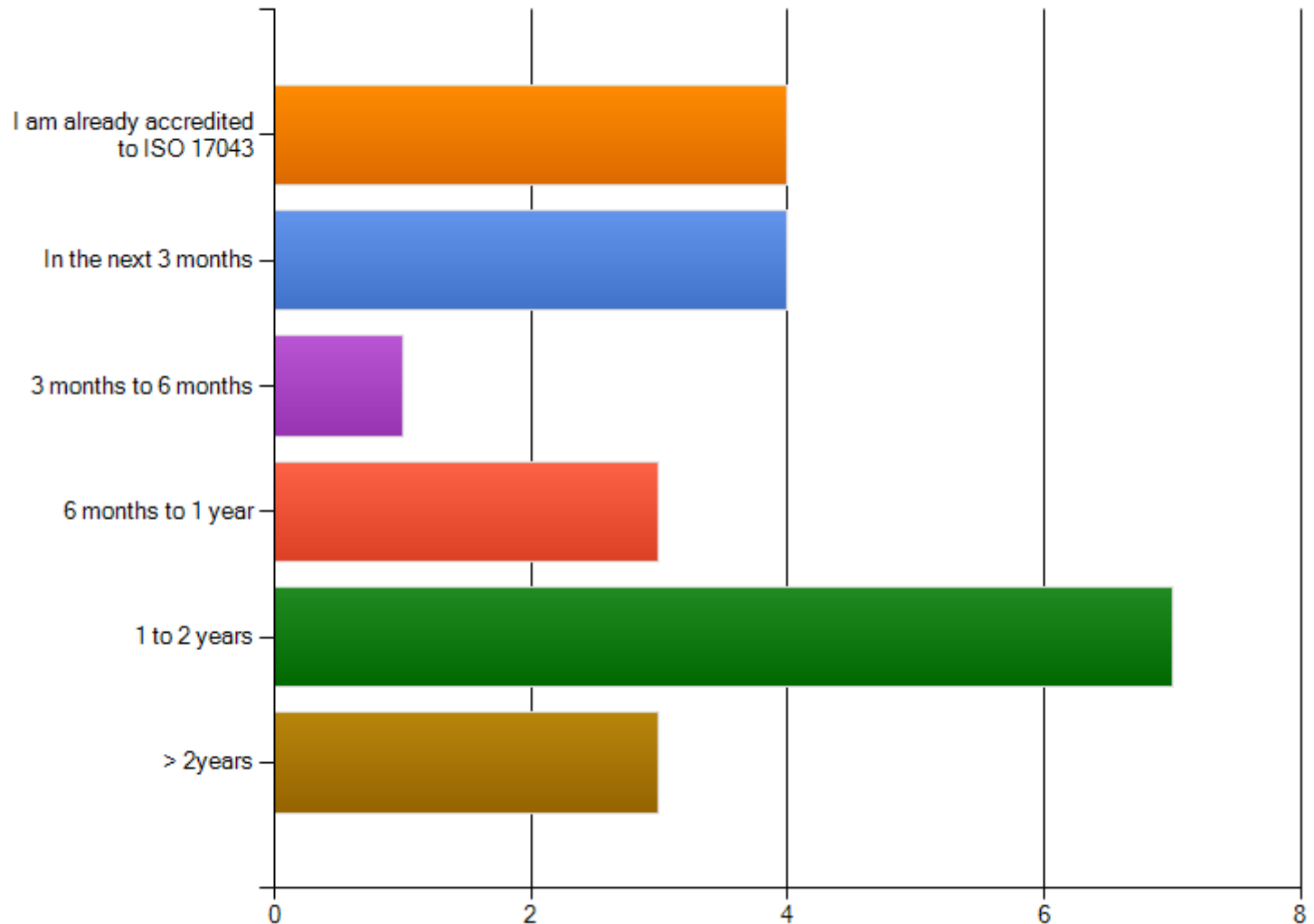
Q.4

Do you intend to seek ISO 17043 accreditation in the near future?



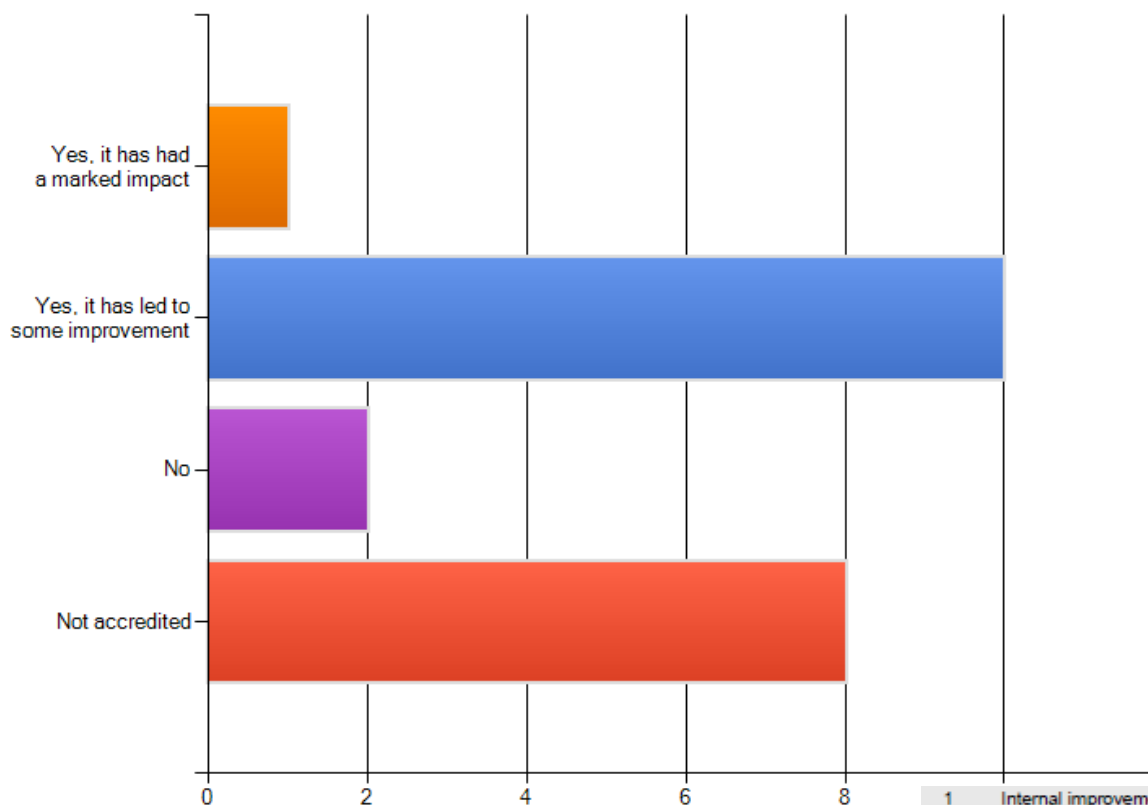
Q.5

What timescale do you anticipate achieving ISO 17043 accreditation?



Q.7

Have you experienced an improvement in the quality of your EQA service since accreditation?

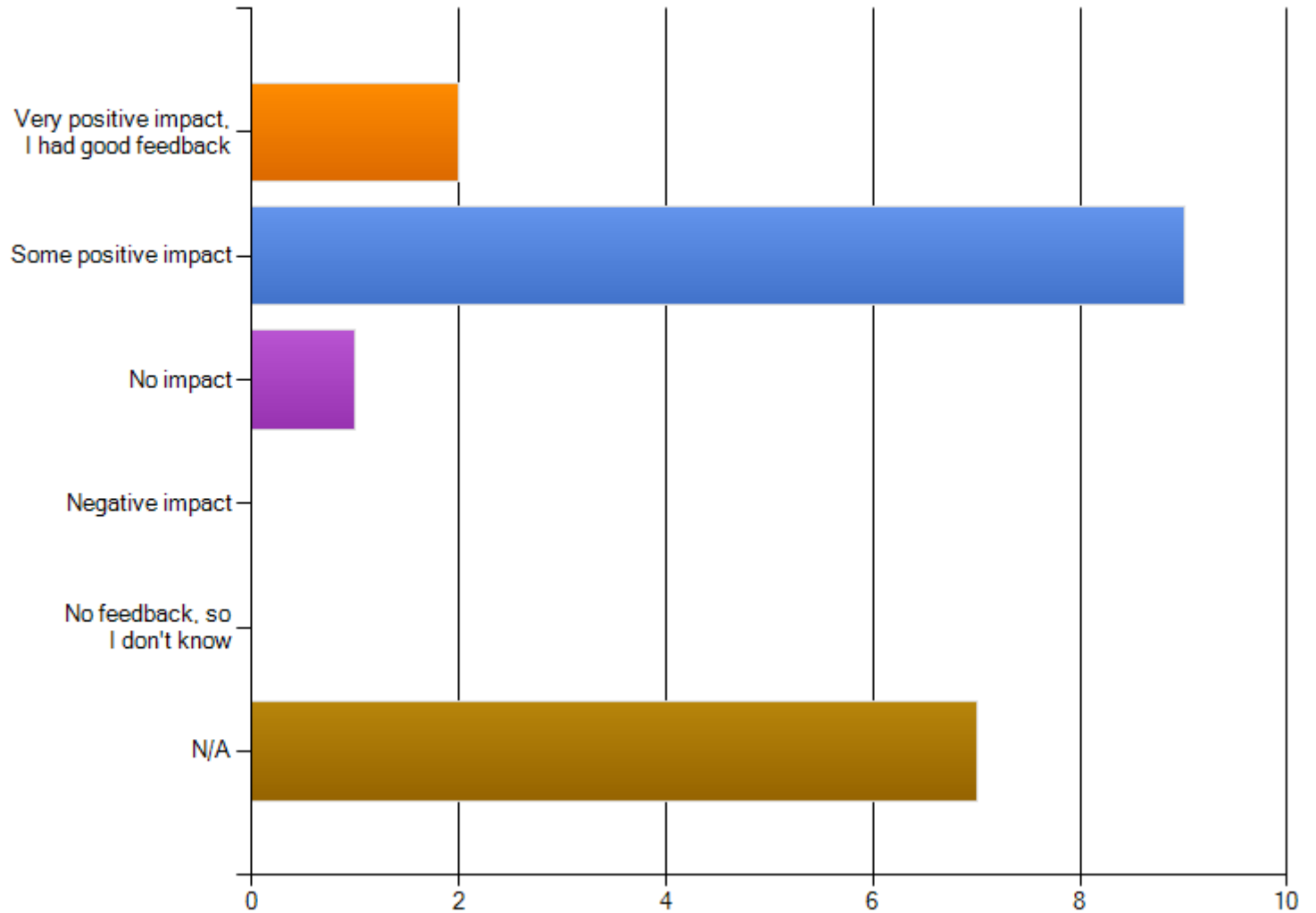


In 2005 84% expected or experienced an improvement

- 1 Internal improvement is the most significant change. Lessons learned and know-how are critical.
- 2 Since certification to ISO 9001:2008, have experienced an improvement not only in quality of service, but in efficiency of operation.
- 3 Even the certification according to NS-EN ISO 9001:2008 have led to improvements and was important for a few of our participants
- 4 Already operating to other ISO standards
- 5 this is difficult to answer. the organisation was first accredited over 15 years ago and there is no documented 'memory'.
- 6 Not so much since actual accreditation but due to changes made in conforming with standard

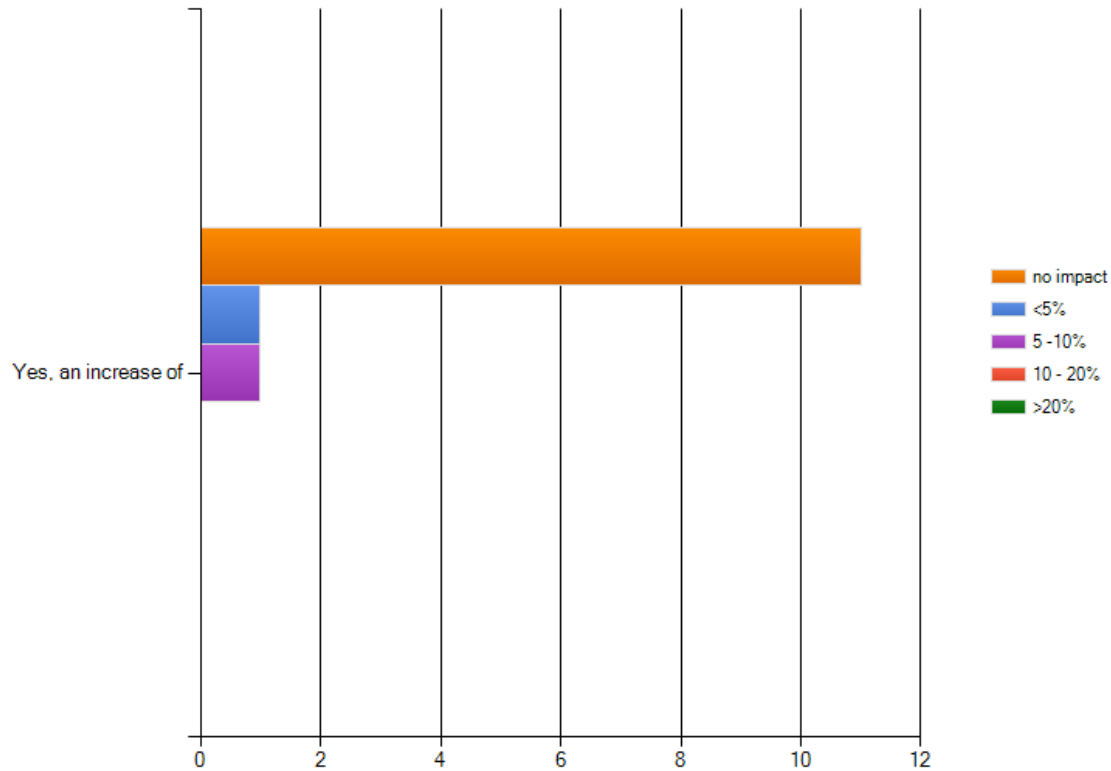
Q.8

What is/was the impact of your accreditation on the customer?



Q.9

Did the accreditation process have an impact on your participation fees
and by how much?

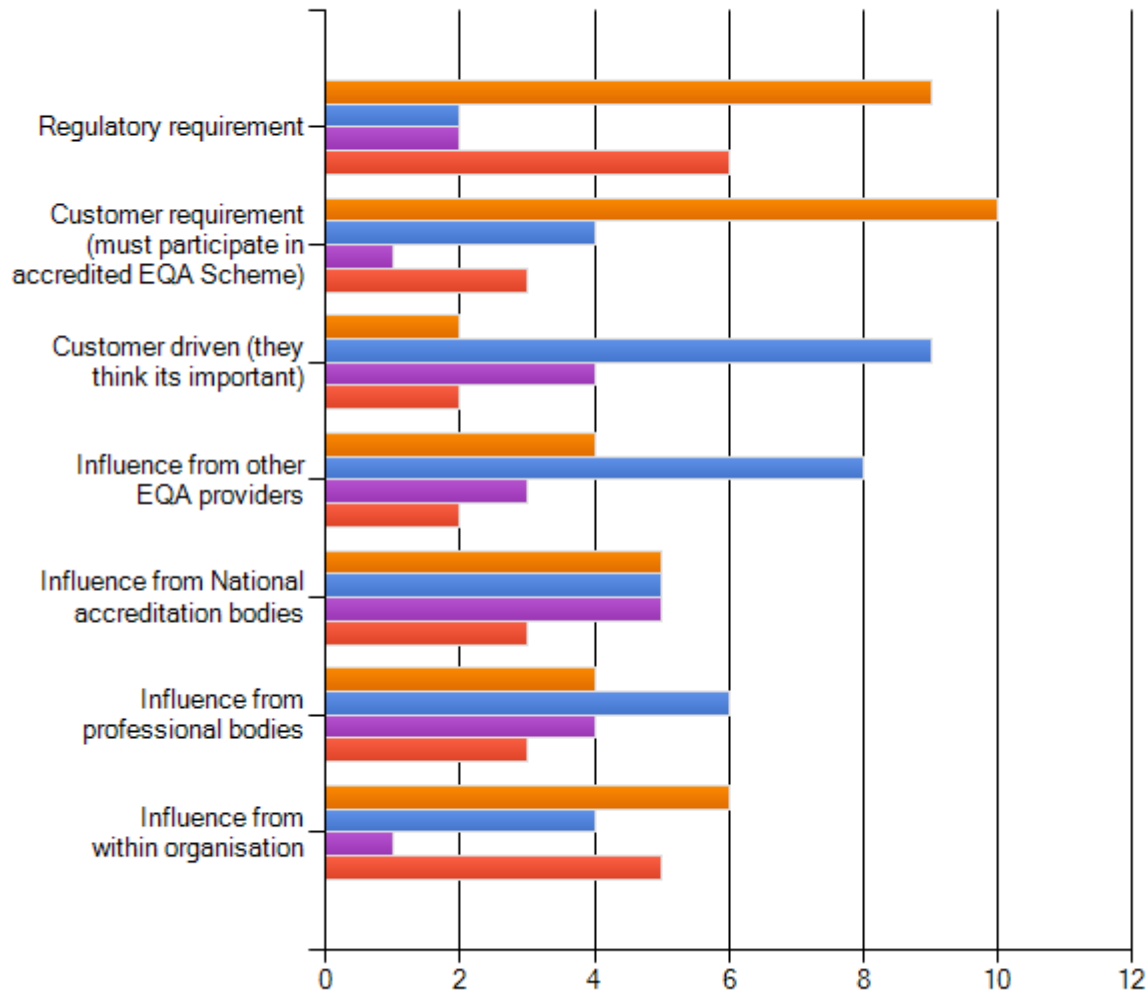


In 2005

Large variation observed of 2- 250%
increase in fees

Q.10

What are/were the reasons for you to apply for accreditation of your EQA Schemes?



Main reason
Some influence
No influence
N/A

In 2005

32% customer driven

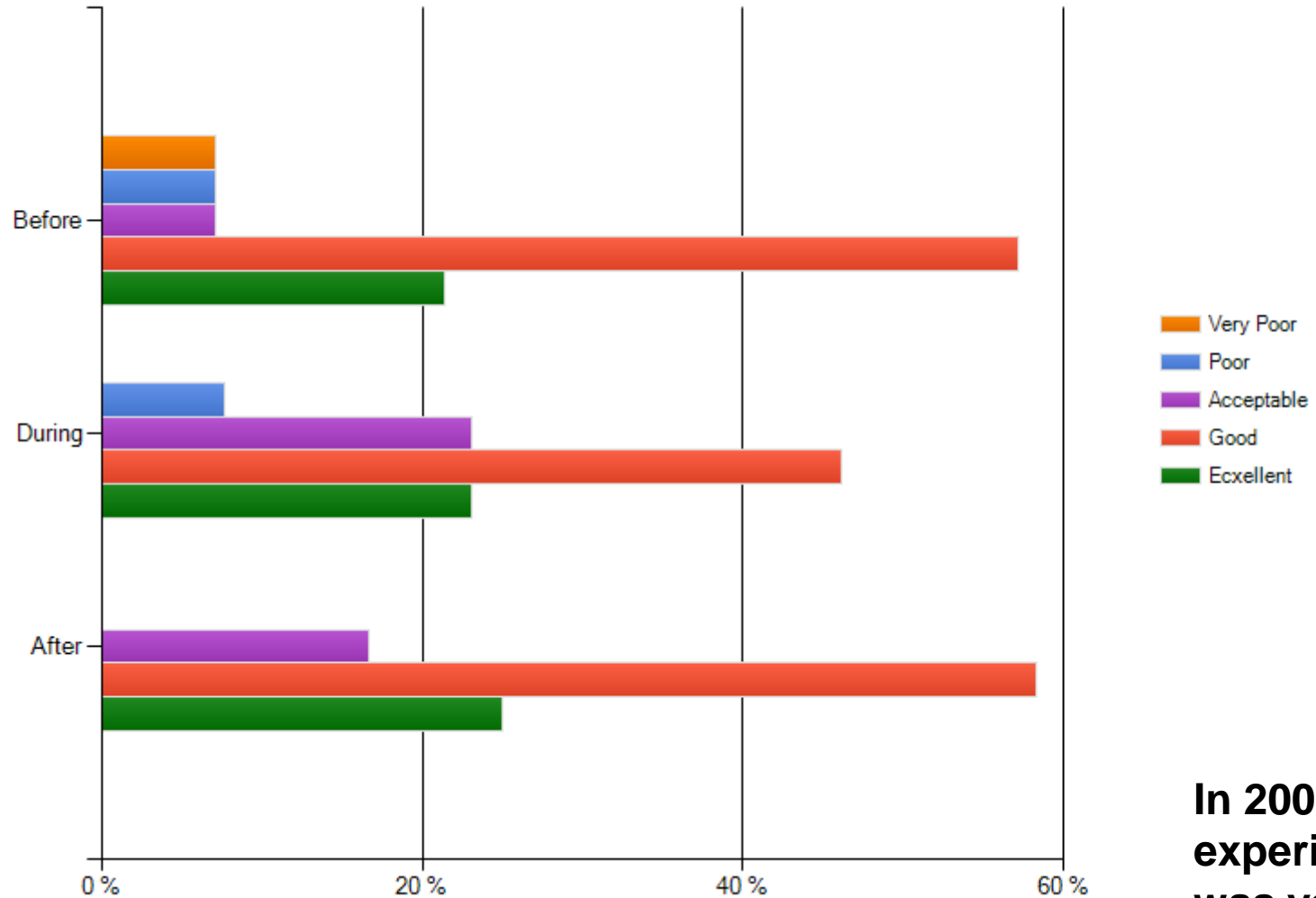
**28% influence from other
EQA organisations**

**23% regulatory
requirement**

**17% influenced by
accreditation body**

Q.11

How do you rate your experience from the contacts/ interactions with the accreditation body, before, during and after the process?



**In 2005
experience
was very
good.**

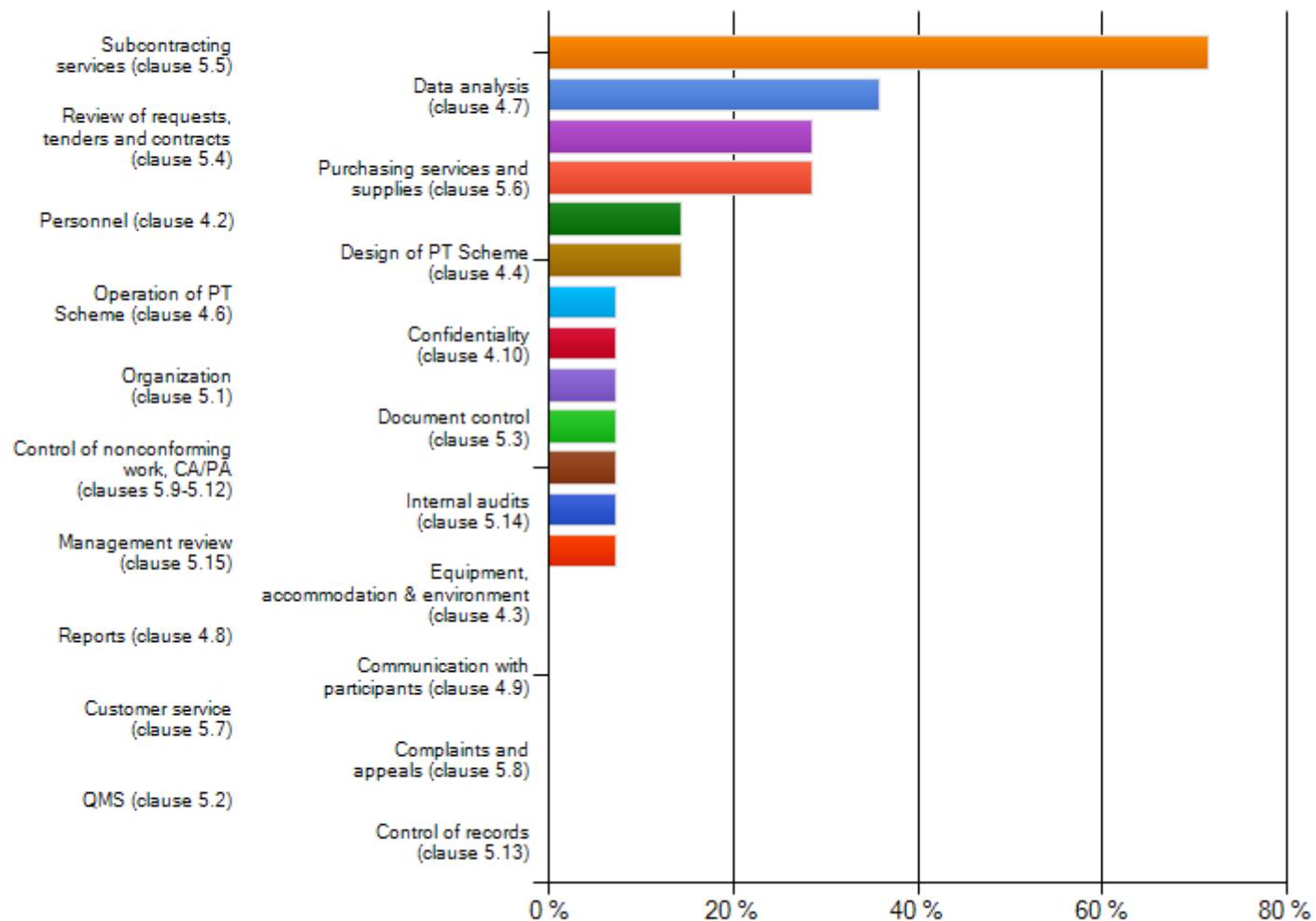
Q.12

Page 3, Q1. Please provide details of your Accreditation body

1	CPA UKAS
2	www.sas.ch
3	www.cai.cz
4	Croatian Accreditation Agency HR-10000 ZAGREB Ulica grada Vukovara 78 Te.:01/6106322 Faks: 01/6106322 www.akreditacija.hr
5	Problems because of new regulation in Germany, DAKKS
6	ZLG and DAkkS
7	Clinical Pathology Accreditation (CPA-UK) "Standards for EQA Scheme in Laboratory Medicine"
8	CPA (UK) Ltd
9	Bureau Veritas Certification Certification of General Management Systems and Internal audit
10	UKAS
11	cpa (eqa) ltd
12	www.sas.ch
13	The American Association for Laboratory Accreditation 5301 Buckeystown Pike Suite 350 Frederick, MD 21704 Phone: 301 644 3248 Fax: 301 662 2974

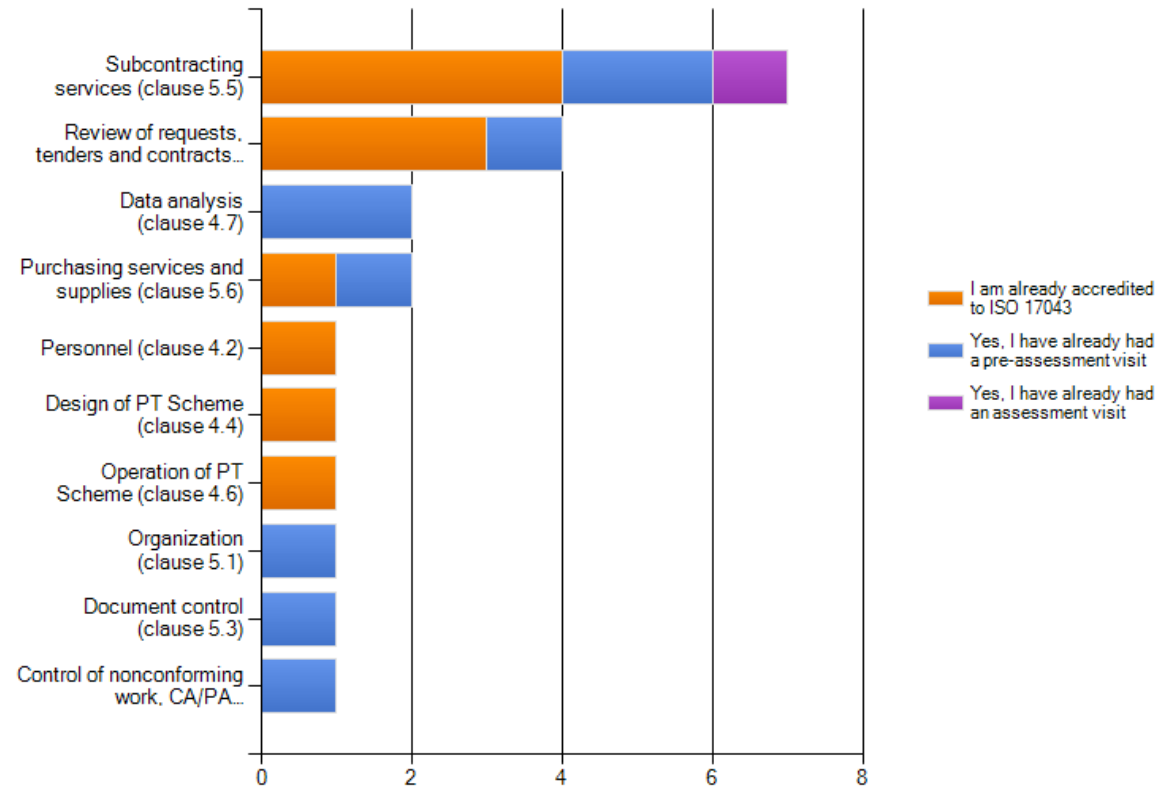
Q.13

Which clause(s) in ISO 17043 do you feel was (or is going to be) the most difficult to achieve ?



Q13 to 9 organisations already assessed

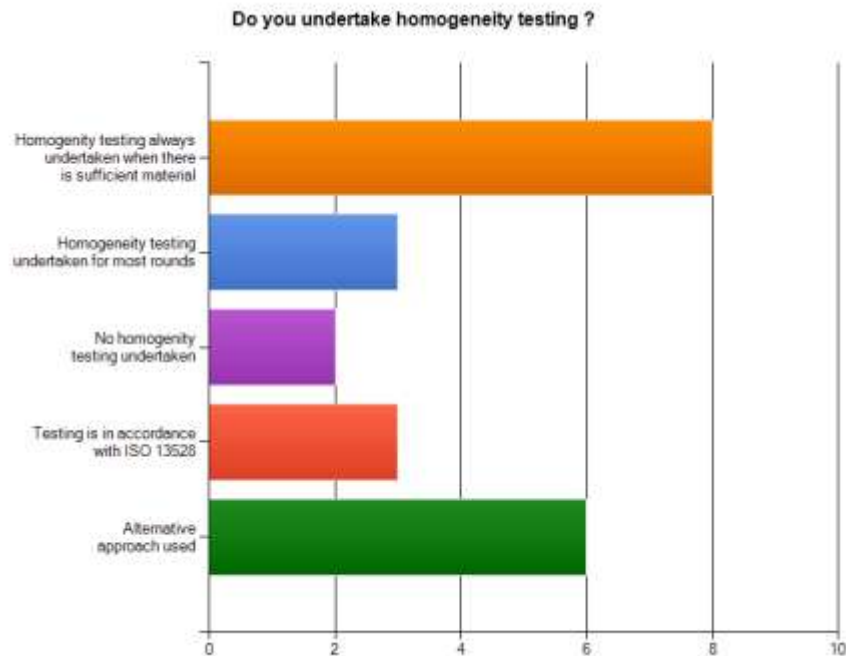
Which clause(s) in ISO 17043 do you feel was (or is going to be) the most difficult to achieve ?



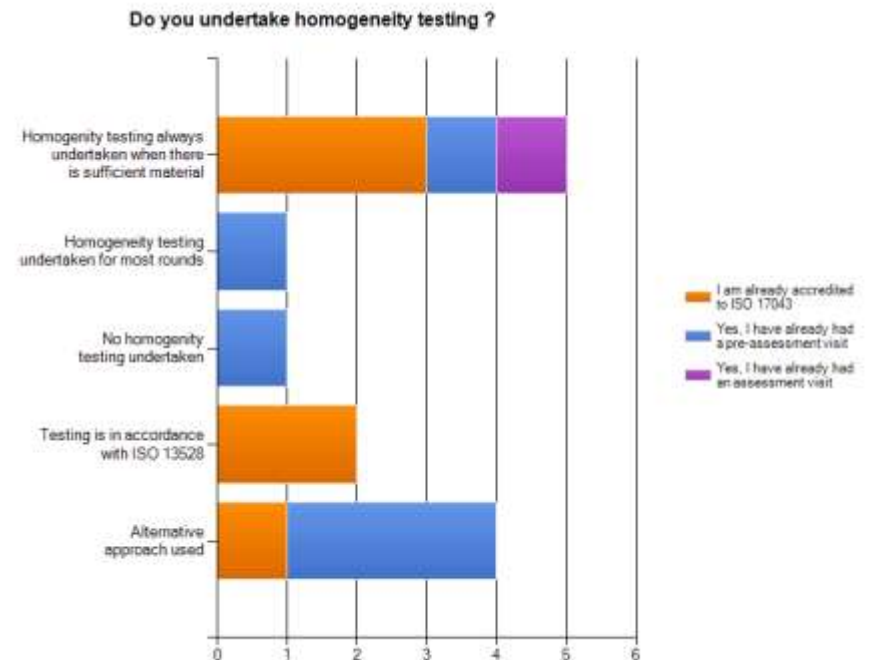
Comments

- 1 Specifically homogeneity and stability, monitoring transportation temperature, competence of subcontractors.
- 2 Centralizing and accessing the IT documents and procedures.
- 3 Homogeneity and stability studies

Q. 14- All responses



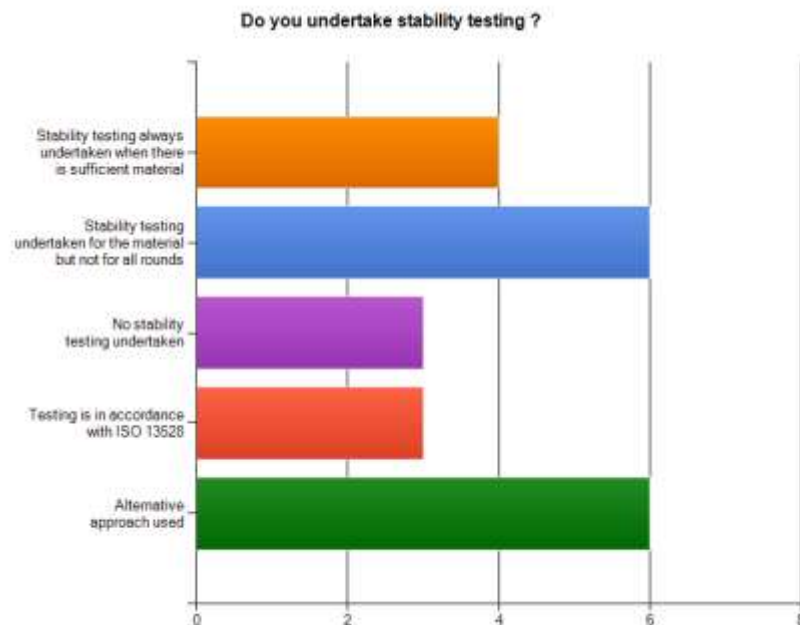
Q.14– Organisations assessed



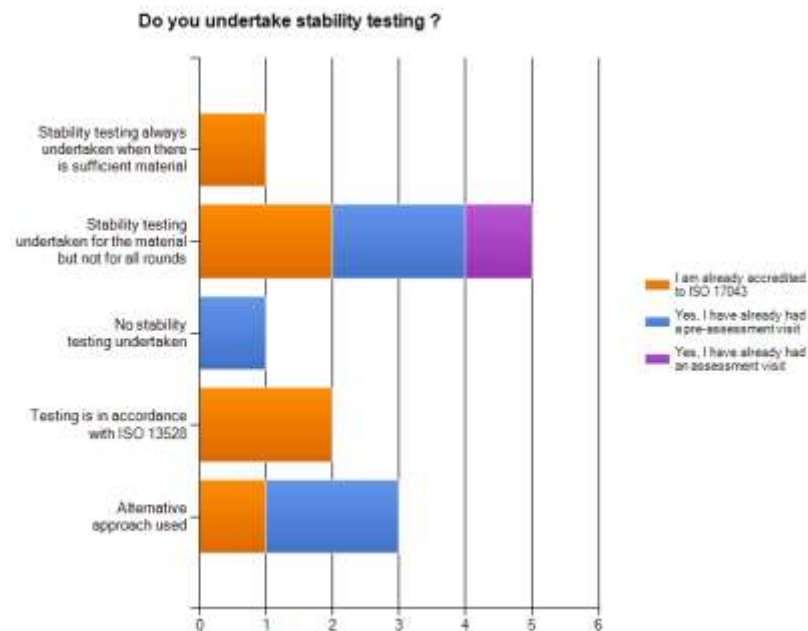
Page 4, Q1. Do you undertake homogeneity testing ?

- 1 Front and back samples of each rack analysed (for trends) rather than random sampling of 10
- 2 Gathering information on Homogeneity from our cproviders. Setting up an internal system for ensuring homogeneity of our own prepared Control materials.
- 3 We do not test commercial (e.g. Directive 98/79/EC compliant) samples.
- 4 homogeneity undertaken on selected samples
- 5 Testing with routine methods in an accredited laboratory according to a given scheme
- 6 Target values with reference measurement procedures for 28 analytes in clinical chemistry
- 7 Manufacturers provide suitable certification to prove the homogeneity of control materials.

Q.15 – All responses



Q.15 – Organisations assessed

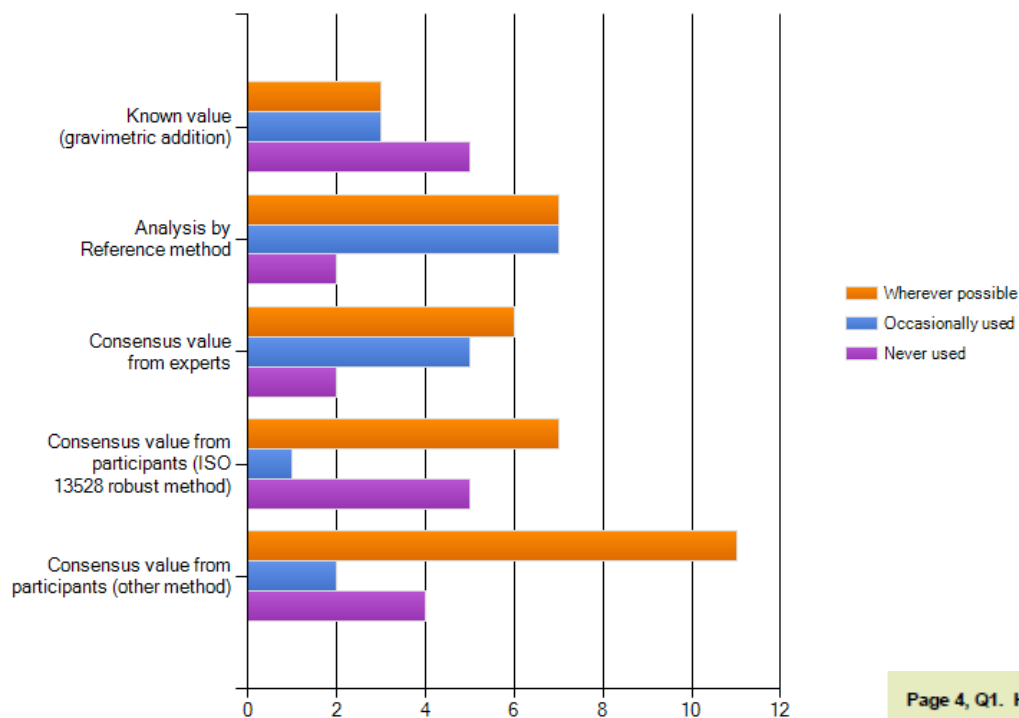


Page 4, Q1. Do you undertake stability testing ?

- 1 Long term - overall mean and SD monitored over length of batch, one storage temperature. Short term stability undertaken - stability assessed at different temperatures over 2 week period, low, med ,high concentrations.
- 2 Stability testing is performed for the approval of each new Control material
- 3 We do not test commercial (e.g. Directive 98/79/EC compliant) samples.
- 4 Manufacturers provide suitable certification to prove the stability of control materials.
- 5 Assessment of submitted results
- 6 For every round some panel is left for control testing after all the participants have recieved their shipment.
- 7 Alternative approach for non-quantitative schemes; also reduced numbers tested when insufficient material.

Q. 16 – All responses

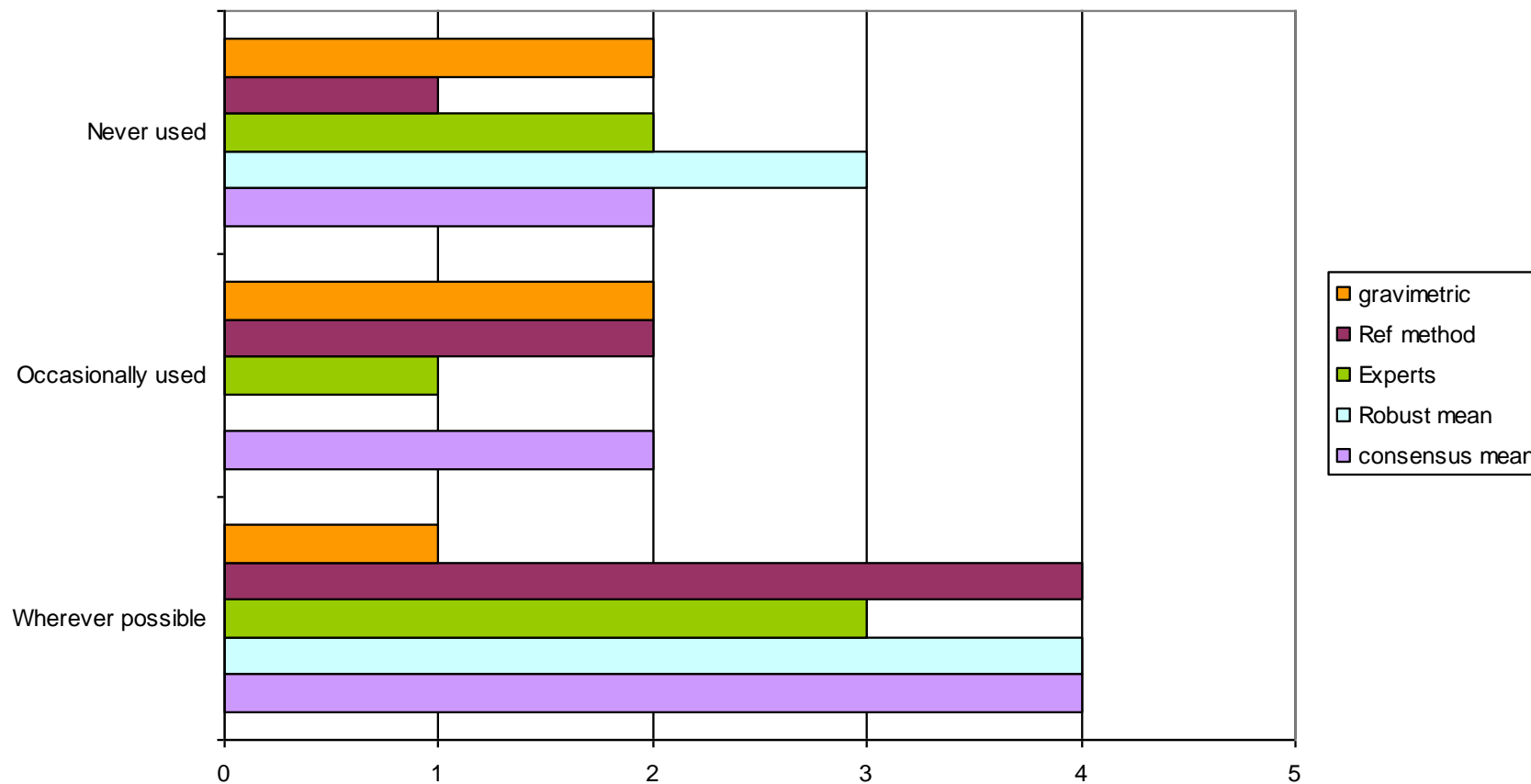
How do you determine the assigned value for your quantitative Schemes?



Page 4, Q1. How do you determine the assigned value for your quantitative Schemes?

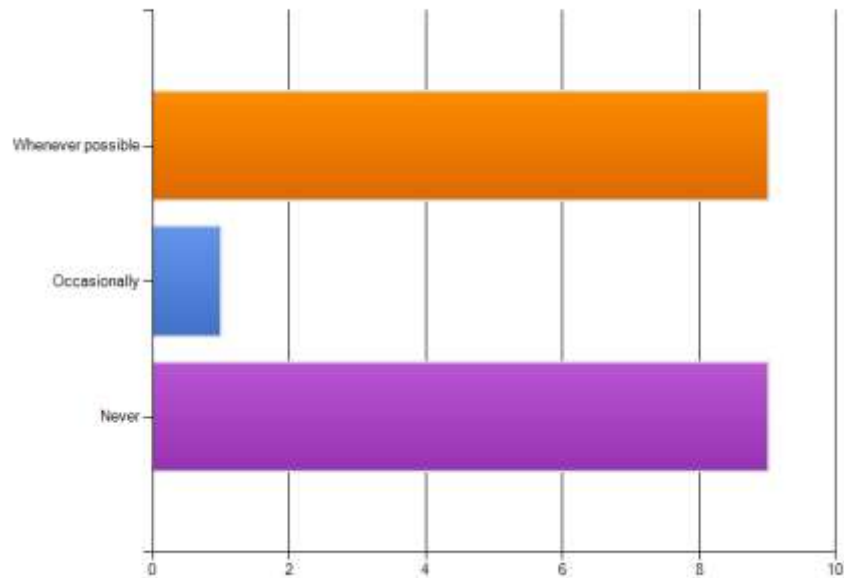
- | | |
|---|---|
| 1 | It depends on each type of surveys. Please contact us for more explanation from us. |
| 2 | European Reference Laboratory used for out HbA1c scheme. |
| 3 | Consensus value is the median calculated after elimination of outliers (median + 3SD robust). SD robust = (75° perc - 25° perc) / 1.349 |

Q.16 – How do you determine the assigned value? Organisations assessed to 17043



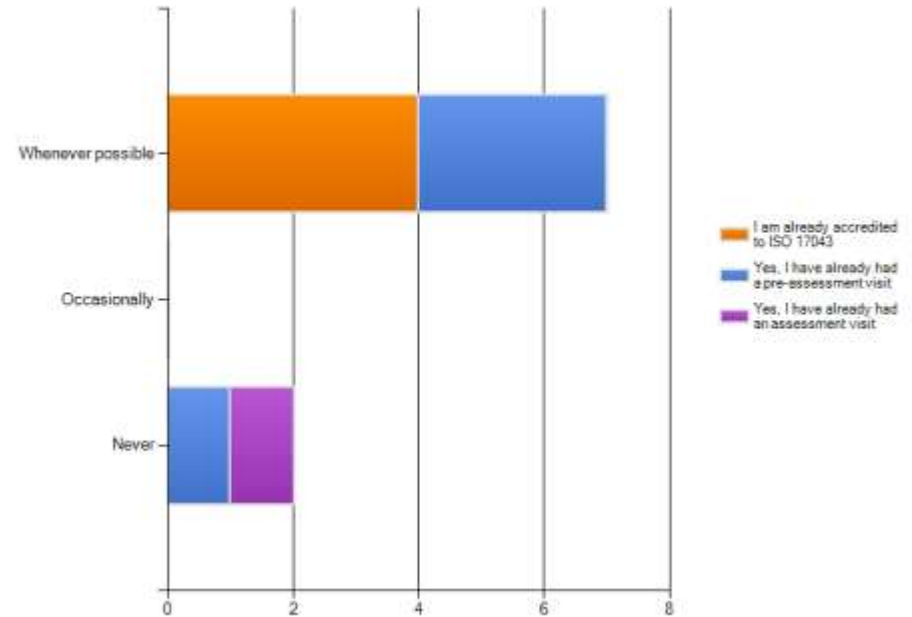
Q.17- All responses

Do you calculate and provide the measurement uncertainty of the assigned value on your reports?



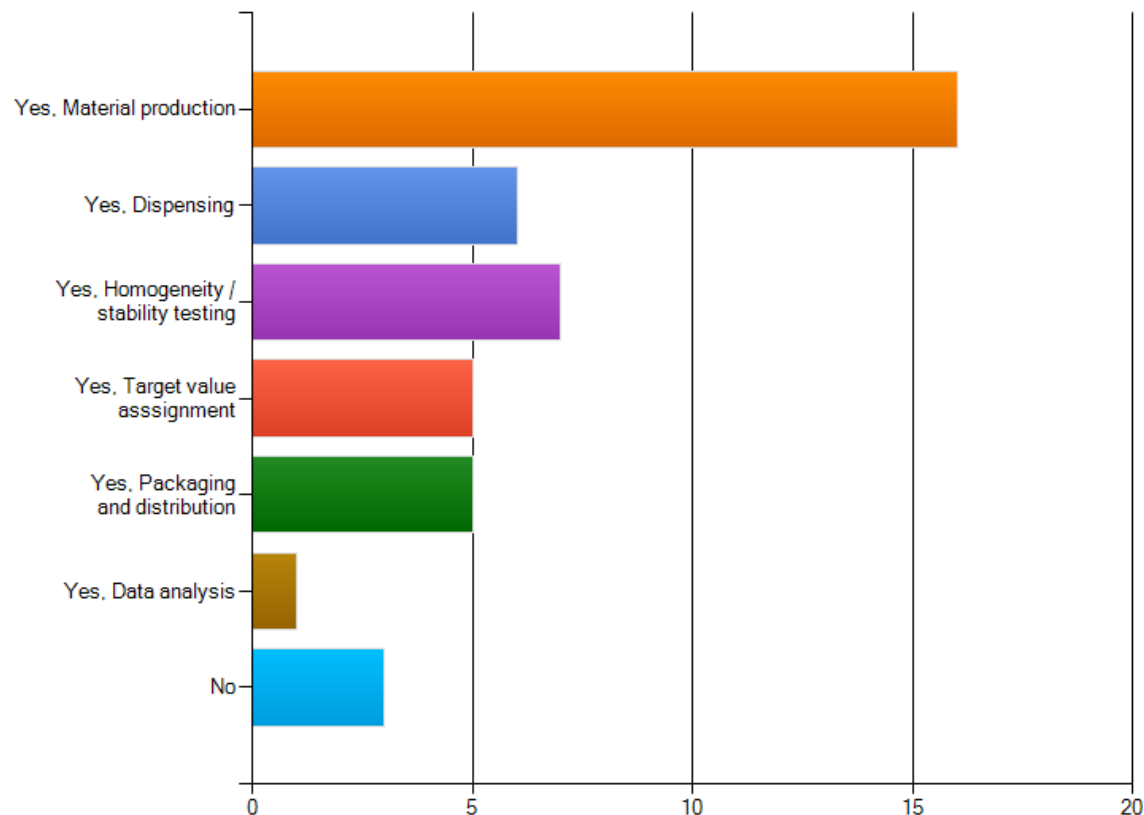
Q.17 – Organisations assessed

Do you calculate and provide the measurement uncertainty of the assigned value on your reports?



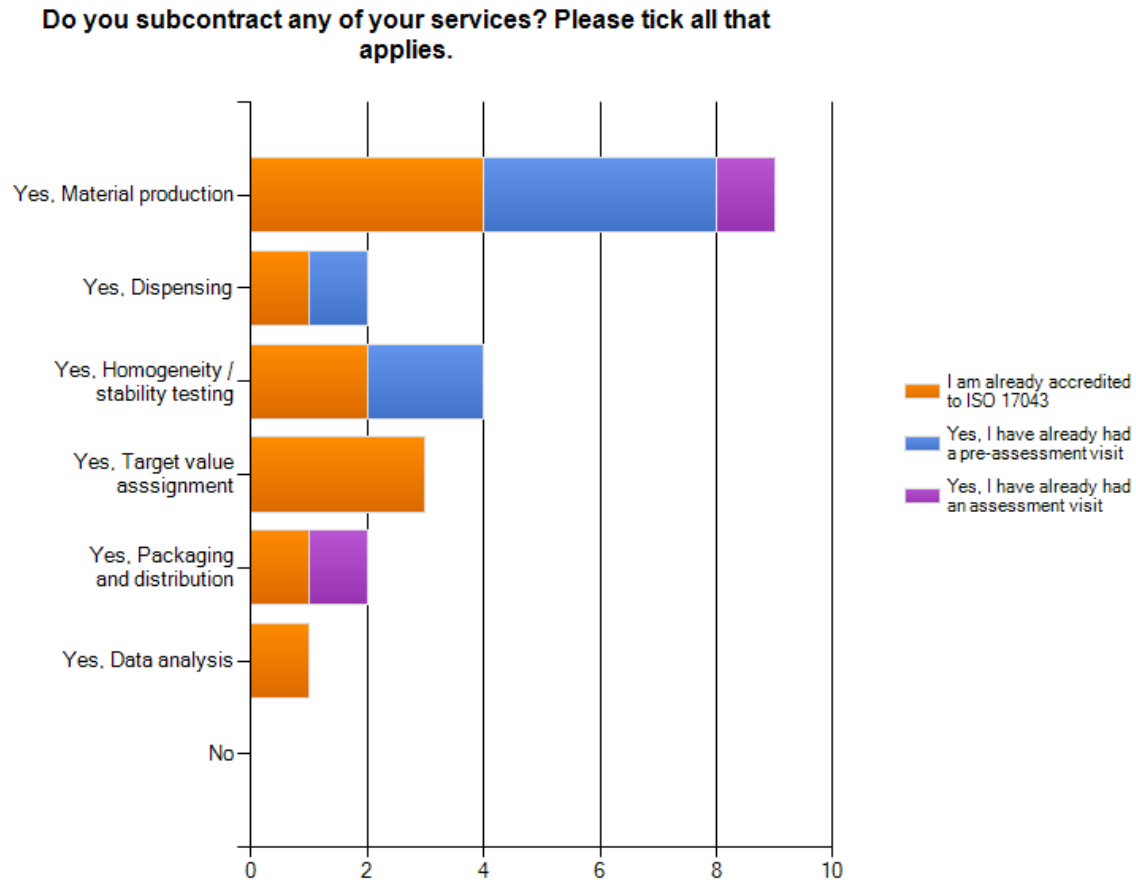
Q. 19

Do you subcontract any of your services? Please tick all that applies.



- | | |
|---|---|
| 1 | It depends on each type of surveys. Please contact us for more explanation from us. |
| 2 | We only operate four schemes ourselves; we are also agents for Labquality who provide the majority of schemes to our customers. |
| 3 | For some schemes (haematology, parasitology, hepatitis serology, molecular biology). |
| 4 | Depending on the programm |
| 5 | For 2 specialised schemes only |
| 6 | only for some samples |

Q19 to 9 organisations already assessed



Thank you for all taking part