Survey on the Accreditation of EQA Schemes in Laboratory Medicine

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UK
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

<table>
<thead>
<tr>
<th>Country</th>
<th>no of Responses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Austria</td>
<td>1</td>
</tr>
<tr>
<td>Canada</td>
<td>1</td>
</tr>
<tr>
<td>Croatia</td>
<td>1</td>
</tr>
<tr>
<td>Czech Republic</td>
<td>1</td>
</tr>
<tr>
<td>France</td>
<td>1</td>
</tr>
<tr>
<td>Germany</td>
<td>2</td>
</tr>
<tr>
<td>Hungary</td>
<td>1</td>
</tr>
<tr>
<td>Ireland</td>
<td>1</td>
</tr>
<tr>
<td>Italy</td>
<td>1</td>
</tr>
<tr>
<td>Netherlands</td>
<td>1</td>
</tr>
<tr>
<td>Norway</td>
<td>1</td>
</tr>
<tr>
<td>Oman</td>
<td>1</td>
</tr>
<tr>
<td>RUS</td>
<td>1</td>
</tr>
<tr>
<td>Spain</td>
<td>1</td>
</tr>
<tr>
<td>Switzerland</td>
<td>2</td>
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<tr>
<td>UK</td>
<td>4</td>
</tr>
<tr>
<td>Unknown</td>
<td>1</td>
</tr>
</tbody>
</table>

Total 22

17 Countries represented
Q.20

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

<table>
<thead>
<tr>
<th>Field</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical Chemistry</td>
<td>80%</td>
</tr>
<tr>
<td>Haematology</td>
<td>70%</td>
</tr>
<tr>
<td>POCT</td>
<td>65%</td>
</tr>
<tr>
<td>Immunology</td>
<td>60%</td>
</tr>
<tr>
<td>Microbiology</td>
<td>50%</td>
</tr>
<tr>
<td>Genetics</td>
<td>30%</td>
</tr>
<tr>
<td>Toxicology</td>
<td>35%</td>
</tr>
<tr>
<td>Cytology</td>
<td>30%</td>
</tr>
<tr>
<td>Histopathology</td>
<td>20%</td>
</tr>
</tbody>
</table>

Page 5, Q4. 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
In 2005 only 28% were accredited
2. Are you accredited for all or some of your Schemes?

<table>
<thead>
<tr>
<th></th>
<th>All</th>
<th>Majority</th>
<th>Some</th>
<th>None</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemistry</td>
<td>43.8% (7)</td>
<td>18.8% (3)</td>
<td>0.0% (0)</td>
<td>18.8% (3)</td>
</tr>
<tr>
<td>Haematology</td>
<td>56.3% (9)</td>
<td>18.8% (3)</td>
<td>0.0% (0)</td>
<td>6.3% (1)</td>
</tr>
<tr>
<td>Histology</td>
<td>27.3% (3)</td>
<td>0.0% (0)</td>
<td>0.0% (0)</td>
<td>27.3% (3)</td>
</tr>
<tr>
<td>Immunology</td>
<td>40.0% (6)</td>
<td>20.0% (3)</td>
<td>0.0% (0)</td>
<td>13.3% (2)</td>
</tr>
<tr>
<td>Genetics</td>
<td>15.4% (2)</td>
<td>23.1% (3)</td>
<td>7.7% (1)</td>
<td>15.4% (2)</td>
</tr>
<tr>
<td>Microbiology</td>
<td>14.3% (2)</td>
<td>21.4% (3)</td>
<td>0.0% (0)</td>
<td>28.6% (4)</td>
</tr>
<tr>
<td>POCT</td>
<td>46.2% (6)</td>
<td>7.7% (1)</td>
<td>0.0% (0)</td>
<td>23.1% (3)</td>
</tr>
</tbody>
</table>
Q.3

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

- ISO/IEC 17043: 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?

- Yes, as a testing or calibration laboratory according to ISO/IEC 17025
- Yes, as a medical testing laboratory to ISO/IEC 15189
- Yes, as a reference measurement laboratory to ISO 15195
- Yes, as a reference material producer to ISO Guide 34
- No

In 2005

20% accredited to ISO 17025 or 15189
Q.4

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

- I am already accredited to ISO 17043
- Yes, I have already applied
- Yes, I have already applied and undertaken a gap analysis
- Yes, I have already had a pre-assessment visit
- Yes, I have already had an assessment visit
- Yes, but not this year.
- No
Q.5

What timescale do you anticipate achieving ISO 17043 accreditation?

- I am already accredited to ISO 17043
- In the next 3 months
- 3 months to 6 months
- 6 months to 1 year
- 1 to 2 years
- > 2 years
Q.7

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

- Yes, it has had a marked impact
- Yes, it has led to some improvement
- No
- Not accredited

In 2005 84% expected or experienced an improvement
Q.8

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

- Very positive impact, I had good feedback
- Some positive impact
- No impact
- Negative impact
- No feedback, so I don't know
- N/A
Q.9

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?

In 2005

- 32% customer driven
- 28% influence from other EQA organisations
- 23% regulatory requirement
- 17% influenced by accreditation body
In 2005 experience was very good.
Page 3, Q1. Please provide details of your Accreditation body

<table>
<thead>
<tr>
<th></th>
<th>Accreditation Body Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>CPA UKAS</td>
</tr>
<tr>
<td>2</td>
<td><a href="http://www.sas.ch">www.sas.ch</a></td>
</tr>
<tr>
<td>3</td>
<td><a href="http://www.cai.cz">www.cai.cz</a></td>
</tr>
<tr>
<td>4</td>
<td>Croatian Accreditation Agency HR-10000 ZAGREB Ulica grada Vukovara 78 Te.:01/6106322 Faks: 01/6106322 <a href="http://www.akreditacija.hr">www.akreditacija.hr</a></td>
</tr>
<tr>
<td>5</td>
<td>Problems because of new regulation in Germany, DAKKS</td>
</tr>
<tr>
<td>6</td>
<td>ZLG and DAkkS</td>
</tr>
<tr>
<td>7</td>
<td>Clinical Pathology Accreditation (CPA-UK) &quot;Standards for EQA Scheme in Laboratory Medicine&quot;</td>
</tr>
<tr>
<td>8</td>
<td>CPA (UK) Ltd</td>
</tr>
<tr>
<td>9</td>
<td>Bureau Veritas Certification Certification of General Management Systems and Internal audit</td>
</tr>
<tr>
<td>10</td>
<td>UKAS</td>
</tr>
<tr>
<td>11</td>
<td>cpa (eqa) ltd</td>
</tr>
<tr>
<td>12</td>
<td><a href="http://www.sas.ch">www.sas.ch</a></td>
</tr>
<tr>
<td>13</td>
<td>The American Association for Laboratory Accreditation 5301 Buckeystown Pike Suite 350 Frederick, MD 21704 Phone: 301 644 3248 Fax: 301 682 2974</td>
</tr>
</tbody>
</table>
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?

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

1. Front and back samples of each rack analysed (for trends) rather than random sampling of 10
2. Gathering information on homogeneity from our suppliers. 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.14– Organisations assessed
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, medium, high concentrations.

2. Stability testing is performed for the approval of each new Control material

3. We do not test commercial (e.g. Directive 98/78/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 received their shipment.

7. Alternative approach for non-quantitative schemes; also reduced numbers tested when insufficient material.
Q. 16 – All responses

- Known value (gravimetric addition)
- Analysis by Reference method
- Consensus value from experts
- Consensus value from participants (ISO 13528 robust method)
- Consensus value from participants (other method)

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 our HbA1c scheme.
3. Consensus value is the median calculated after elimination of outliers (median + 3SD robust). SD robust = (75th perc - 25th 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?

- Whenever possible
- Occasionally
- Never

Q.17 – Organisations assessed

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

- Whenever possible
- Occasionally
- Never

Color codes:
- Orange: I am already accredited to ISO 17025
- Blue: Yes, I have already had a pre-assessment visit
- Pink: Yes, I have already had an assessment visit
Q. 19

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

- Yes, Material production
- Yes, Dispensing
- Yes, Homogeneity / stability testing
- Yes, Target value assignment
- Yes, Packaging and distribution
- Yes, Data analysis
- No

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 programme
5. For 2 specialised schemes only
6. only for some samples
Q19 to 9 organisations already assessed
Thank you for all taking part