

ILAC Laboratory Survey on Conversion to ISO/IEC 17025

A Report by Bryce McNair, Survey Co-ordinator, on behalf of the ILAC Laboratory Committee

Introduction

In 2003, the ILAC Laboratory Committee decided that a survey should be undertaken to test the extent to which there were on-going problems faced by laboratories in relation to the conversion from accreditation to ISO/IEC 17025 from previous laboratory accreditation standards.

A brief survey form was distributed to accredited laboratories twice through accreditation bodies in early 2004. The response exceeded expectations – a return rate of five percent is usually thought acceptable whereas this survey attracted responses from over ten percent of the population. There are some notable gaps – for example, the results do not express the views of laboratories in Sweden, France or New Zealand.

While the sample is self-selected and therefore lacks the representativeness of a random collection, the survey results could be said to indicate the range of views held by the managers of accredited laboratories around the world. The responses were sent direct to the Convenor on the basis that their answers would not be revealed in an identifiable way to their accreditation body or others, thus giving laboratories the opportunity to express honest opinions. This factor lends particular power to the survey results.

There were major problems in handling of the considerable amount of data represented by over 2,000 survey forms (mostly emailed but with over 300 faxes) and the survey could not have been completed without the application of significant blocks of time by the staff of NATA Australia. It is recommended that future global surveys of laboratories be collected online which would obviate the need for manual data capture. While unprompted questions and provision for comments allow analysts to get a richer understanding of the opinions of respondents, they are probably not worth the considerable extra time involved to record and assess them.

The Response

The responses received from 51 countries are summarised in Table 1. Laboratories were asked to specify the fields of testing for which they were accredited and it is likely that the lack of an international standard for the classification of testing fields led to some confusion amongst laboratory managers and makes it difficult to judge which sectors have been under-represented. Chemical laboratories accounted for nearly half of the sample with significant numbers of responses from calibration and metrology and from mechanical testing.

A surprisingly small number declined to provide identifying information. They have been included where they have answered significant portions of the survey.

ILAC Laboratory Survey on Introduction of ISO/IEC 17025

Summary of Responses

Country	Testing	App Physics		Chemical	Electrical		Info Tech		Medical	Non-Destruct				
	Calibration	Biology	Construction	Forensic	Mechanical	Metrology	Vetinary							
ARGENTINA	14	5	3	1	7	3	5	0	0	3	0	6	2	0
AUSTRALIA	212	26	8	29	80	32	15	6	4	47	32	20	12	7
AUSTRIA	61	4	14	12	38	13	8	0	2	11	3	4	14	5
BANGLADESH	2	0	0	0	2	0	0	0	0	2	0	0	0	0
BELGIUM	62	7	2	6	32	10	4	3	0	5	7	6	5	6
BRAZIL	34	25	5	1	14	8	8	2	0	8	0	21	6	0
BRUNEI	1	1	0	0	1	0	1	0	0	1	0	1	0	0
CANADA	84	13	1	29	61	4	10	3	1	18	0	13	4	3
CHINA	51	10	8	8	28	6	14	1	6	13	3	7	1	1
CROATIA	0	1	0	0	0	0	0	0	0	0	0	1	0	0
CYPRUS	5	2	0	3	2	1	0	1	0	1	2	2	0	0
DENMARK	27	9	2	5	11	3	6	1	0	5	5	10	1	1
ECUADOR	3	0	0	3	3	0	0	0	0	0	0	0	0	0
ESTONIA	1	0	0	0	0	1	0	0	0	0	0	0	0	0
FINLAND	24	5	0	9	14	1	0	0	0	2	4	6	0	0
FRANCE	1	0	0	0	0	0	0	0	0	0	0	0	1	0
GERMANY	71	7	5	0	2	1	46	0	12	14	1	6	5	0
GREECE	13	3	0	0	10	0	3	0	1	3	1	3	0	0
HONG KONG	19	4	1	2	8	5	5	0	0	3	3	6	3	0
HUNGARY	91	28	4	20	48	5	9	1	0	14	3	26	12	1
INDIA	64	26	1	9	38	2	14	1	1	36	10	19	4	1
INDONESIA	118	31	30	21	78	9	7	0	1	18	5	26	4	9
IRELAND	19	2	0	8	15	0	0	1	0	0	0	2	1	1
ISRAEL	13	0	0	5	9	1	2	0	0	0	0	0	1	0
ITALY	7	45	1	0	2	2	8	0	0	7	0	42	1	0
JAPAN	65	10	1	2	36	6	12	0	1	11	0	5	0	0
JORDAN	1	1	0	1	1	1	1	0	0	1	0	1	1	0
KENYA	1	0	0	1	1	0	0	0	0	0	0	0	0	0
LITHUANIA	1	0	0	1	1	0	0	0	0	0	0	0	0	1
MALAYSIA	37	8	1	7	29	2	7	0	0	11	1	5	2	1

Summary of Responses (Continued)

Country	Testing	App Physics		Chemical	Electrical		Info Tech		Medical	Non-Destruct				
	Calibration	Biology	Construction	Forensic	Mechanical	Metrology	Veterinary							
MEXICO	4	3	0	0	2	1	0	0	0	1	0	3	0	0
NETHERLANDS	42	16	6	5	22	7	6	0	1	9	3	11	4	1
PERU	2	0	0	0	2	0	0	0	0	0	0	0	0	0
PHILIPPINES	3	1	0	0	1	1	0	0	0	0	0	1	0	0
POLAND	98	5	54	22	57	17	14	0	0	16	2	6	5	0
PORTUGAL	63	14	6	9	31	6	3	0	0	7	3	14	4	0
ROMANIA	31	2	6	3	16	6	5	0	2	6	3	2	0	0
RUSSIA	1	0	0	0	0	0	0	0	0	1	0	0	0	0
SINGAPORE	17	6	0	5	7	5	2	0	1	5	2	7	1	1
SLOVAKIA	23	5	0	4	15	3	1	0	0	3	1	5	3	1
SOUTH AFRICA	40	1	2	9	26	4	3	0	0	2	1	2	1	2
SOUTH KOREA	57	9	0	8	25	6	18	0	3	20	1	6	4	0
SPAIN	46	23	6	13	40	6	5	2	3	10	3	22	1	2
SWITZERLAND	108	22	11	19	30	9	10	1	1	12	31	22	3	12
SYRIA	1	0	0	0	1	0	0	0	0	0	0	0	0	0
TAIWAN	0	0	0	0	0	0	1	0	0	0	0	0	0	0
THAILAND	20	3	2	5	11	2	0	0	0	2	1	2	0	1
TUNISIA	1	0	0	1	0	0	0	0	0	0	0	0	0	0
UGANDA	2	0	0	2	1	0	0	0	0	0	0	0	1	0
UNITED KINGDOM	101	31	3	18	43	18	13	6	2	14	1	26	11	6
UNITED STATES	68	18	1	3	23	14	11	0	1	40	2	16	8	0
VIETNAM	3	0	0	3	3	0	0	0	0	0	0	0	0	0
ZIMBABWE	2	0	0	0	0	0	0	0	0	0	0	1	0	0
UNSPECIFIED	1	1	0	0	1	0	0	0	0	1	0	1	0	0
Total	1836	433	184	312	928	221	277	29	43	383	134	385	126	63

Table 1. Summary of responses by country and field of testing.

Note that individual laboratories will have ticked at least two boxes (say Testing and Chemical) but may be accredited for a range of fields. An indication of the total responses for each country may be gained by combining the first two columns although a small number of laboratories are accredited for both testing and calibration.

The Results

Issues in ISO/IEC 17025 Conversion

Respondents were asked to indicate whether the four nominated topics (“laboratory management”, “method validation”, “estimation of uncertainty” and “traceability”) had been an issues for them during the transition and, if so, whether the issue had been resolved. There was also scope for laboratory managers to nominate other topics that had caused problems but virtually no other topics were raised.

The results are summarised in the Table 2 and Figure 1. They indicate that there is ongoing concern about the issue of estimation of uncertainty required by the new standard amongst over 15 percent of respondents.

	Laboratory Management	%	Method Validation	%	Estimate Uncertainty	%	Traceability	%
Had Issue	1239	58.4	1156	53.9	1382	64.5	1027	48.0
Still Have Issue	188	8.9	247	11.5	352	16.4	222	10.4
No Issue	693	32.7	740	34.5	409	19.1	890	41.6
	2120	100	2143	100	2143	100	2139	100

Table 2. “What were/are the major issues for your laboratory in the conversion from accreditation to ISO Guide 25 or EN 45001 to accreditation to ISO/IEC 17025:1999?”

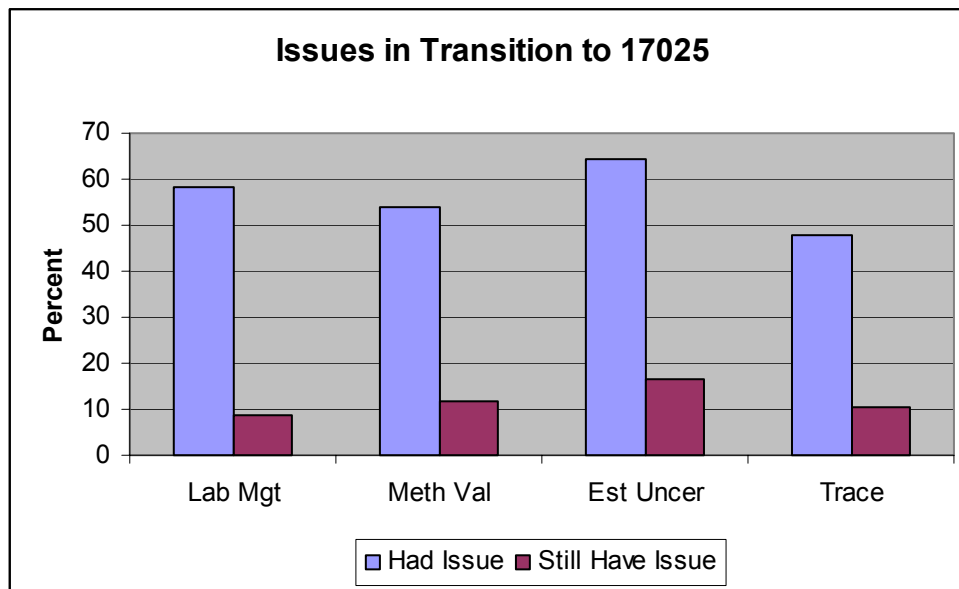


Figure 1. Summary of Table 2

Confidence About On-going Compliance

Respondents were asked to indicate the level of their agreement or disagreement with the following statement “**The key staff in our laboratory know enough about ISO/IEC 17025 to maintain our accreditation.**”

The results are summarised in Table 3 and Figure 2. If there had been a significant proportion of respondents unable to express an opinion or having doubts about staff knowledge of the requirements of the new standard this question would have suggested that there was a major problem. The results indicate that laboratory managers are generally confident that the transition has been successful.

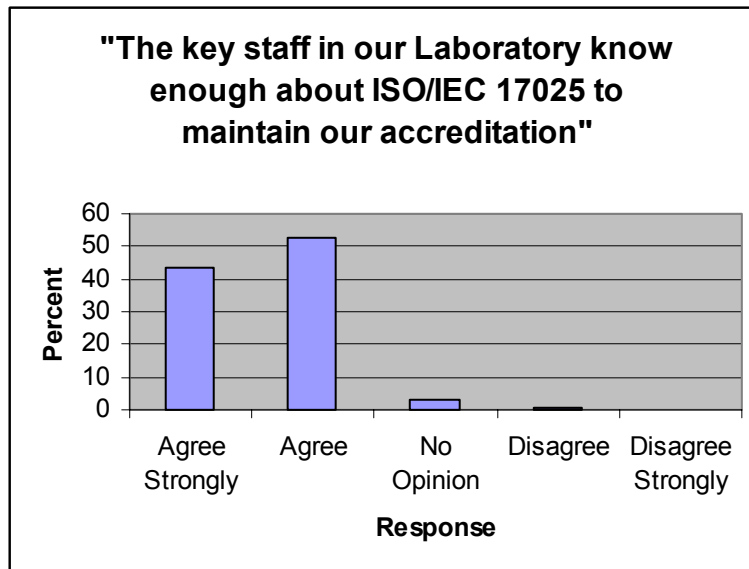


Figure 2.

	Number	Percent
Agree Strongly	928	43.5
Agree	1119	52.4
No Opinion	67	3.1
Disagree	19	0.9
Disagree Strongly	2	0.1
	2135	100.0

Table 3 "The key staff in our laboratory know enough about ISO/IEC 17025 to maintain our accreditation."

Sources of Information Related to ISO/IEC 17025

This question asked respondent to rate the amount and quality of the information on issues related to ISO/IEC 17025 available from a range of sources (accreditation bodies, laboratory associations, governments, professional bodies, standards bodies, ILAC, regional bodies and academic bodies).

The results summarised in Table 4 and Figures 3 and 4 suggest that laboratory managers are generally very happy with the help they received from accreditation bodies. Other sources received mixed reviews which is to be expected given national variations. Disappointment in the level of help from government appears to be a global phenomenon. One interpretation of the results is that ILAC could play a more prominent role in assisting laboratories with future changes to accreditation standards.

	AB	Lab Assoc	Govts	Profess	Standards	ILAC	Regional	Academic
Very Good	30.9	5.2	3.2	2.4	7.7	5.1	1.1	1.3
Good	43.9	20.8	11.1	13.6	25.9	14.9	6.7	6.1
Satisfactory	20.0	22.4	16.7	18.9	23.4	17.9	11.7	11.0
Poor	3.0	10.9	18.1	13.2	10.7	8.1	10.9	13.3
Very Poor	0.5	4.4	14.4	7.7	5.1	3.9	7.9	10.7
No Opinion	1.6	36.3	36.5	44.1	27.1	50.0	61.7	57.6
	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0

Table 4 "How would you rate the amount and quality of the information on issues related to ISO/IEC 17025 available from the following sources?"

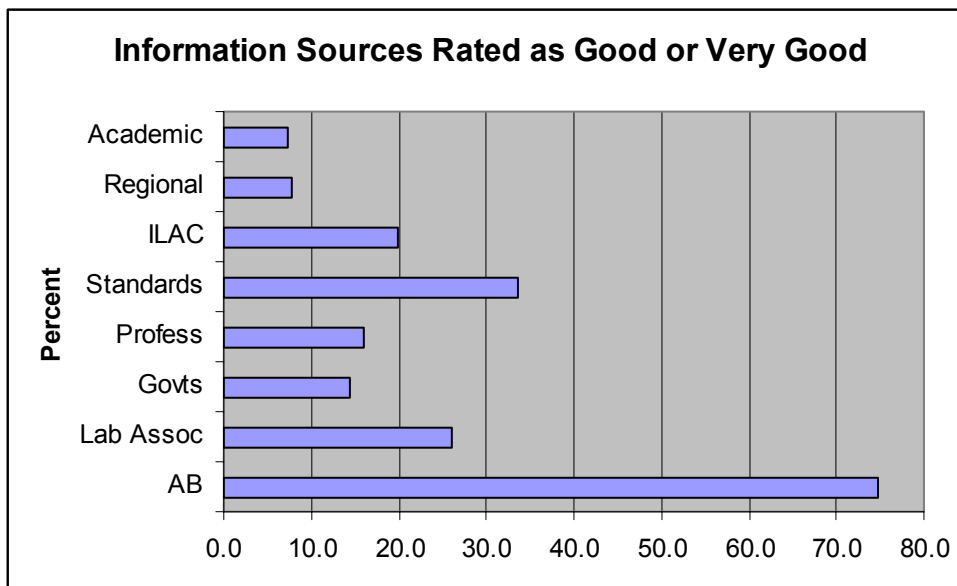


Figure 3

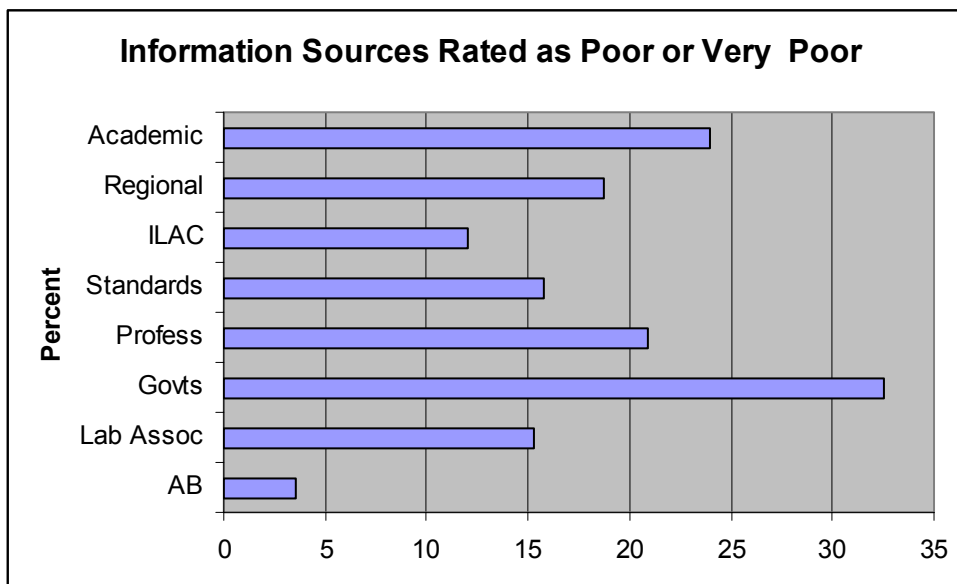


Figure 4

Further Training and Help Required for Laboratories

Respondents were asked "In relation to your laboratory's accreditation to ISO/IEC 17025, what issues do you need most information/training in now?" and invited to nominate up to three issues unprompted.

The two major issues were uncertainty of measurement (865) and method validation (350) but a number of others were mentioned, including

- Inter-laboratory Comparisons (111)
- Traceability (92)
- Laboratory Management (67) – both the need for general training in laboratory management and training in laboratory management systems
- Internal Audits (60)
- Staff Training (53) – often referring to the need for general training opportunities for new technical staff
- Calibration (52)

- Software Validation/LIMS issues (35)
- Corrective/Preventative Actions (33)
- QA/QC and Statistics (24)
- Document Control (22)
- Reference Materials (21)
- Management Review (13)
- Sampling (13)
- Equipment Validation (10) – a small number of laboratory managers specifically requested better information on future changes to the laboratory accreditation standard
- Changes to 17025 (10)
- Environmental Issues (10)

It is important to note that most laboratories did not answer this question indicating that they did not see the need for further training and assistance. There were fewer than 1900 issues nominated out of a potential total of 6477 (2159 respondents by 3). However, the fact that 40 percent sought further assistance in dealing with the standard’s requirements relating to uncertainty of measurement points to a clear need for further information and training.

This was the one question where the responses from the largest field – chemical laboratories – diverged from the mean, being more likely than the whole sample to require further training and assistance in both measurement uncertainty (45.8 percent compared to 40.1 percent) and method validation (23.4 percent compared to 16.2 percent).

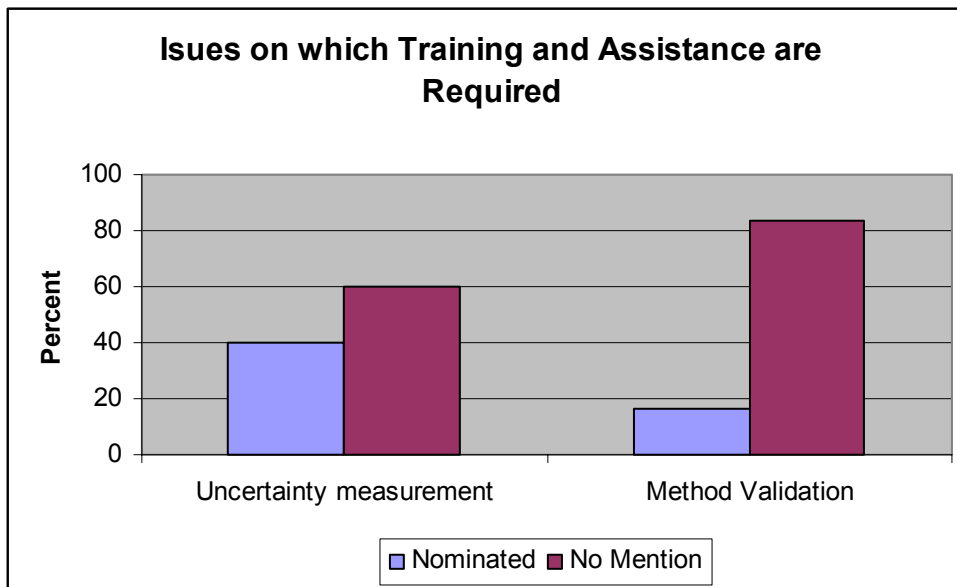


Figure 5

	Uncertainty measurement	Percent	Method Validation	Percent
Nominated	865	40.1	350	16.2
No Mention	1294	59.9	1809	83.8
Total	2159	100.0	2159	100.0

Table 5 Main issues nominated by respondents as requiring further training and assistance.

Laboratory Accreditation Versus Certification

Laboratory managers were asked to express a view on whether the new laboratory accreditation standard had enhanced the distinction between laboratory accreditation and certification. A majority (67%) thought that it had which suggests that the distinction is important to laboratory managers.

Many of those who disagreed commented that the distinction was not understood or appreciated outside of laboratories and the new laboratory accreditation standard had not done anything to improve the situation. Almost none of the respondents who agreed with the statement made useful comments explaining their view.

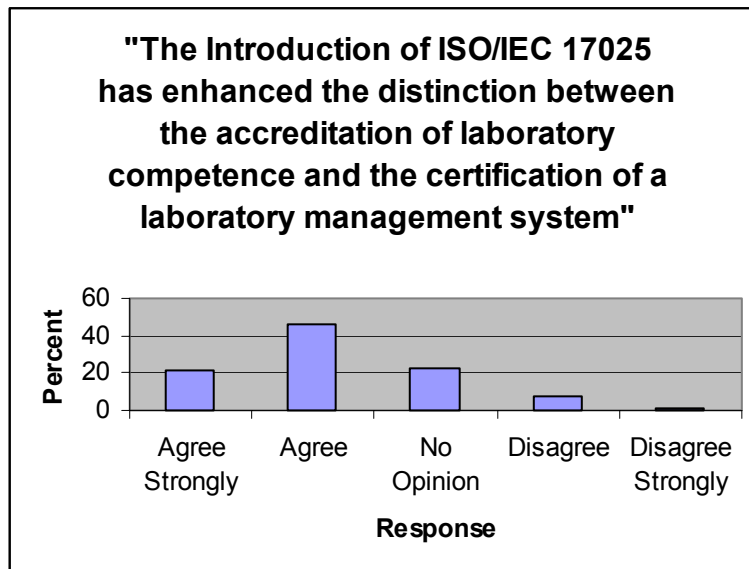


Figure 6

Agree Strongly	468	22.0
Agree	466	46.6
No Opinion	479	22.6
Disagree	72	7.2
Disagree Strongly	33	1.6
	1000	100.0

Table 6 Response to "The introduction of ISO/IEC 17025 has enhanced the distinction between the accreditation of laboratory competence and certification of a laboratory management system."

Attitudes to Further Changes to ISO/IEC 17025

The main lesson from this question is that over 60 percent of laboratories do not favour changes to the standard at this time, their comments indicating that they are still consolidating the new standard. The 15 percent who disagreed tended to favour the early alignment of the laboratory accreditation standard with ISO 9000:2000. A significant proportion, nearly a quarter, did not understand the issues well enough to comment.

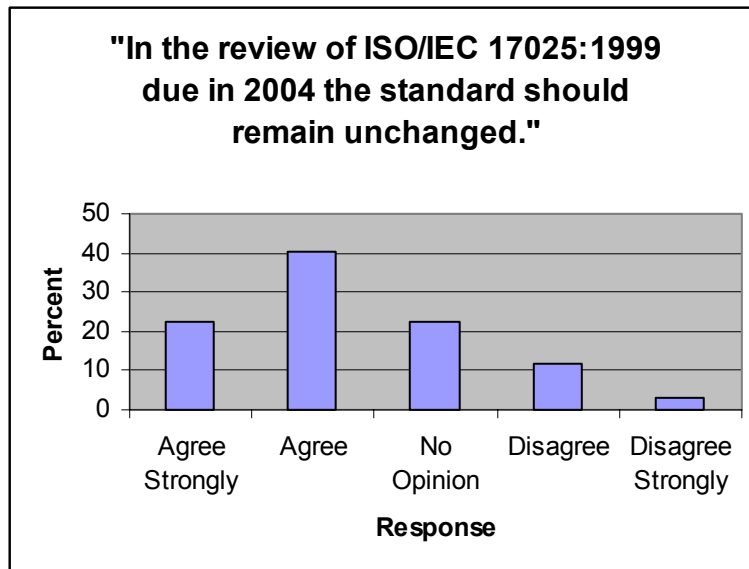


Figure 7

Agree Strongly	477	22.3
Agree	860	40.3
No Opinion	476	22.3
Disagree	253	11.9
Disagree Strongly	68	3.2
	2134	100.0

Table 7 Response to "In the review of ISO/IEC 17025:1999 due in 2004 the standard should remain unchanged."

Perspectives on the Conversion Process

Considering the extent of the changes in the laboratory accreditation standard, the difficulty of some of the issues raised and the fact that some of them are not fully resolved, it is remarkable that the laboratory community generally considers that the transition has gone smoothly. A miniscule proportion took the opportunity to berate ILAC or their accreditation body for inadequate preparation or assistance.

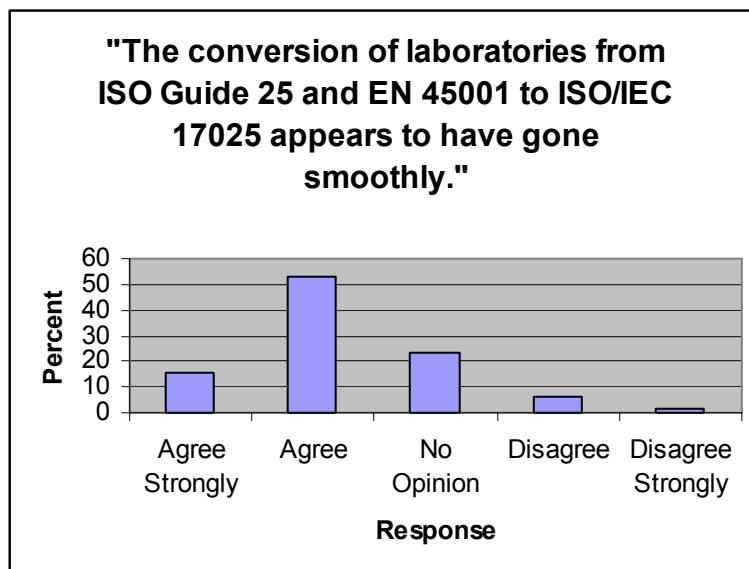


Figure 8

Agree Strongly	334	15.7
Agree	1137	53.3
No Opinion	494	23.3
Disagree	136	6.4
Disagree Strongly	28	1.3
	2129	100.0

Table 8 Response to "The conversion of laboratories from ISO Guide 25 and EN 45001 to ISO/IEC 17025 appears to have gone smoothly"

The Value of Laboratory Accreditation

The results indicate that most laboratories are happy to be accredited. Those that are not so pleased tended to complain about the cost and inconvenience of the standard and the accreditation process.

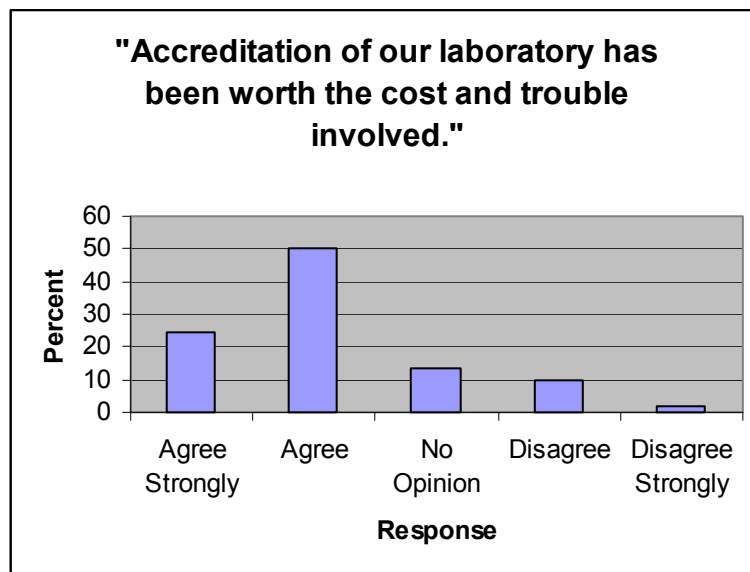


Figure 9

Agree Strongly	525	24.7
Agree	1071	50.2
No Opinion	289	13.6
Disagree	204	9.6
Disagree Strongly	41	1.9
	2130	100.0

Table 9 Response to "Accreditation of our laboratory has been worth the cost and trouble involved."

Inter-laboratory Comparisons, the Laboratory Perspective

This question indicates that laboratories value inter-laboratory comparisons, despite the complaints about cost and delays in receiving results. The main reason for dissatisfaction was that proficiency testing was not available to the respondent's laboratory. The comments confirm that laboratory managers see such comparisons as an important part of their accreditation and professionalism.

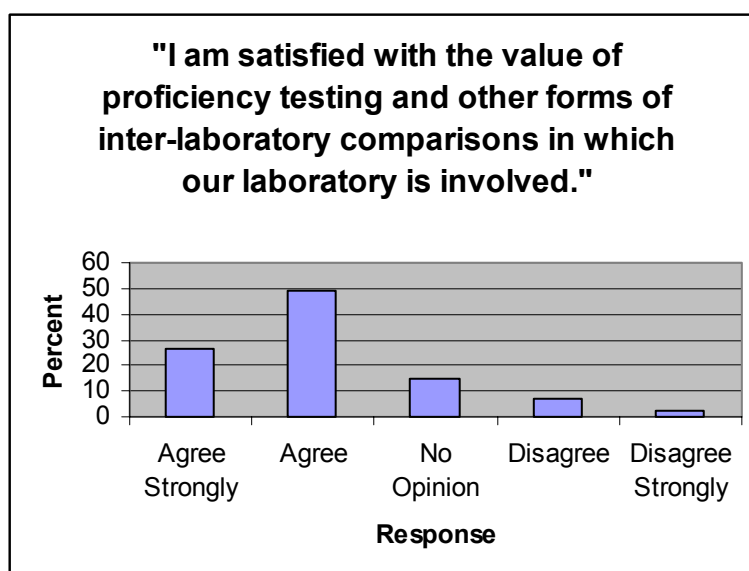


Figure 10

Agree Strongly	566	26.6
Agree	1045	49.2
No Opinion	316	14.9
Disagree	151	7.1
Disagree Strongly	48	2.2
	2126	100.0

Table 10 Response to "I am satisfied with the value of proficiency testing and other forms of inter-laboratory comparisons in which our laboratory is involved."

Conclusions

The global laboratory community appears to have coped well with the significant changes wrought by the introduction of ISO/IEC 17025 as the laboratory accreditation standard. While there are some remaining issues, particularly with regard to estimation of uncertainty and method validation, the survey indicates that the bulk of laboratories around the world have accepted the new requirements.

On the other hand, the survey showed that, as late as May 2004, further training and other assistance was still required on a range of issues, notably estimation of uncertainty, method validation, inter-laboratory comparisons, traceability and the suite of topics included in quality management systems for laboratories. Many respondents pointed to the need for further training opportunities for laboratory managers and technical staff on the specific requirements of ISO/IEC 17025 and more generally.

The performance of accreditation bodies in informing laboratories of the new requirements was generally well rated by laboratory managers.

A majority of laboratories would prefer that they be allowed to consolidate their operations to the new system before further changes are made to the accreditation standard. A small minority expressed support for early alignment of the laboratory accreditation standard with ISO 9000:2000.

Strong majorities of respondents considered that laboratory accreditation is a good investment and that proficiency testing and other inter-laboratory comparisons provide good value.

Overall, the survey reinforces the laboratories' own perspective that the conversion of laboratories around the world to the new accreditation standard has gone smoothly.