Considerations on the efficacy of accreditation and laboratory performance

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Why Become Accredited?

- "Laboratory accreditation is a means of *determining the technical competence* of laboratories to *perform* specific types of testing, measurement and calibration.
- It also provides formal *recognition to competent laboratories*, thus providing a ready means for customers to identify and select *reliable testing, measurement* … services able to meet their needs."

ILAC "Why Become an Accredited Lab" B2:05/2011

Accreditation

It Should Work, Does it?

- Management & Technical Process Check
  - ISO 17025 is a useful outline
- Does accreditation truly reflect competent performance?
- Is accreditation a good indicator of accurate analysis & interpretation?

- THESE ARE TOUGH QUESTIONS!

What Would We Like to See?

Analytical Performance: Sufficient & Improving

- Reliability
- Reproducibility
- Precision
- Accuracy
- Sensitivity/Specificity
- Uncertainty
- Interpretation/Applicability/Significance

How can we tell if accreditation is effective?

- Compare Accredited and Nonaccredited Lab Performance
- Look for Sustained Good Performance or Improvement in Individual Lab Performance after Accreditation
- *Measure* Analytical Performance:
  - Interlab Comparison, Proficiency Testing, Control Charts, Reference Material Measurement, Method Development Round Robins, …

Literature Background

- Several papers compare accreditation status and proficiency test performance
- The conclusions are very mixed from:
  - accredited labs perform worse
  - perform about the same
  - all the way to perform better.
- What are we to believe?

Papers showing no impact

- For all tests and worse within scope only

Table 5 Effect of third-party assessment on PT performance

Laboratory covered by third-party assessment	Number of results	Percentage of results		
		Satis-factory	Ques-tionable	Un-satis-factory
Yes	16291	80	8	12
No	6358	77	8	15

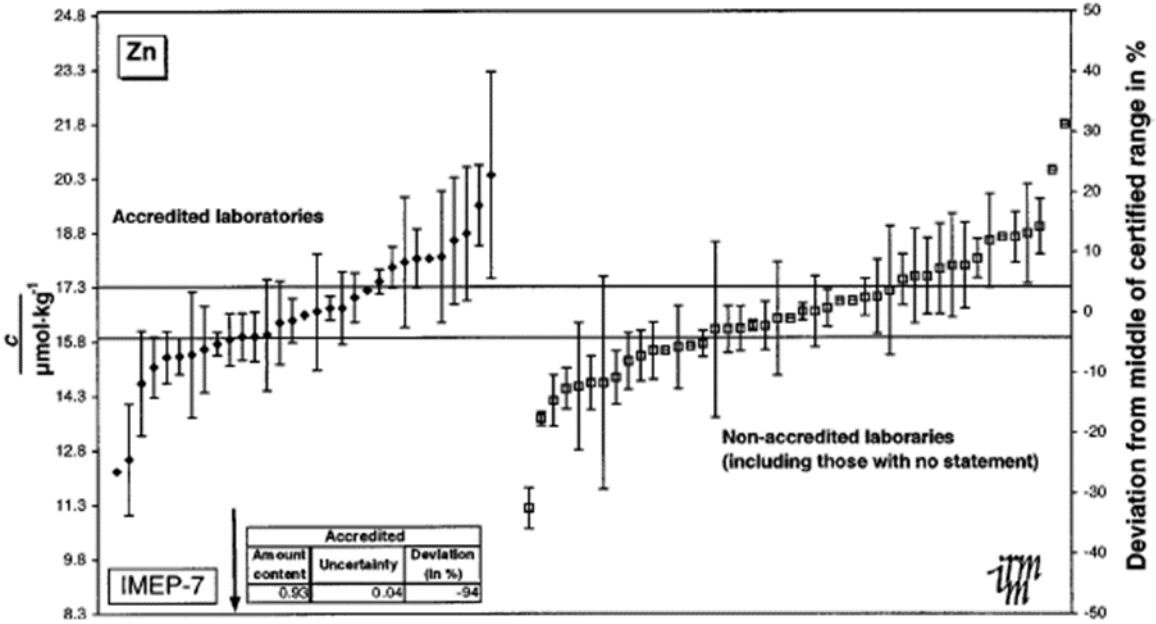
Table 7 Effect of accreditation scope on PT performance

Test within accredited scope	Number of results	% Satisfactory results				% Unsatisfactory results			
		All schemes	BAPS	CONTEST	WEQAS	All schemes	BAPS	CONTEST	WEQAS
Yes	1857	69	86	54	79	19	8	33	4
No	16499	82	86	72	81	11	8	19	3

"The overall conclusion from this study is that there is not evidence from the present study that laboratories with third-party assessments (accreditation or certification) perform any better than laboratories without."

King et al. (1999) Accred. Qual. Assur. 4, 280-291

Another example



All reported results for Zn in human serum. Result outside +/- 50 % from the reference value are found in the text box. No difference noted between accredited and non-accredited laboratories.

From: The IRMM International Measurement Evaluation Programme (IMEP) IMEP-7: Inorganic components in human serum

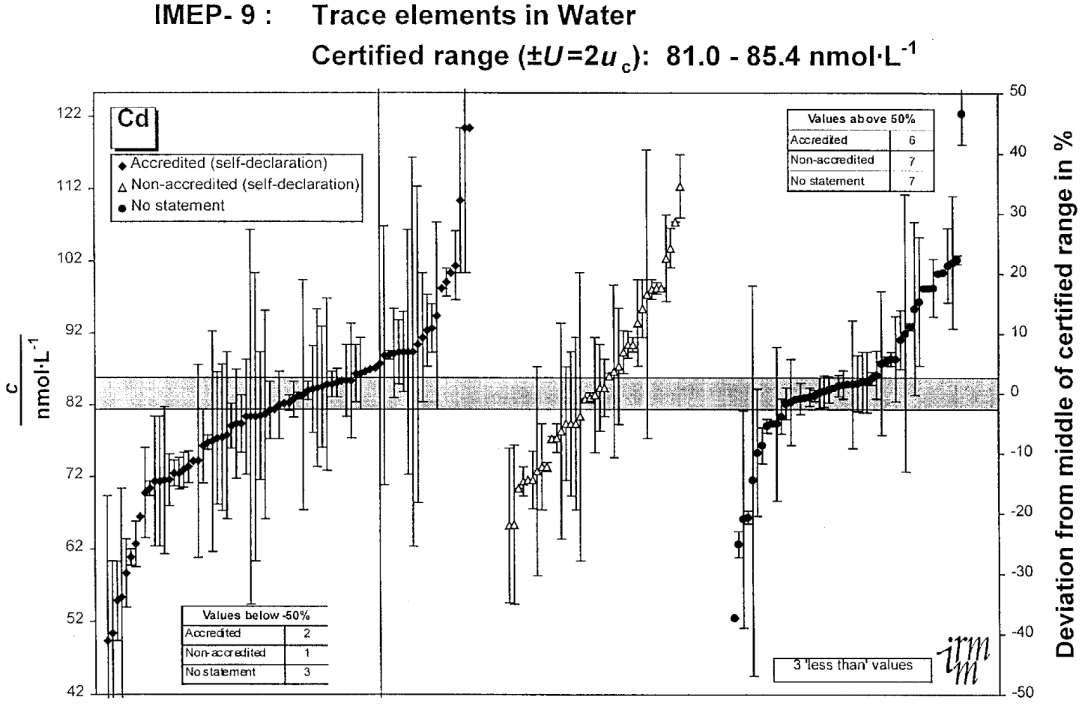
Ornemark et al. (1999) Accred. Qual. Assur. 4, 463-472.

"A sensitive topic discussed in recent years is the relationship between accreditation status and laboratory performance in PT schemes…
King et al. investigated the correlation of laboratory performance in PT with several other quality assurance characteristics. Four PT schemes in a wide range of areas including clinical chemistry were examined."

"The overall conclusion was that laboratories with third-party assessment (accreditation and certification) performed no differently than laboratories without. Neither this study nor other recent IMEP rounds on water, plastic materials and car exhaust catalysts have come to a different conclusion."

Ornemark et al. (1999) Accred. Qual. Assur. 4, 463-472.

This time in water analysis

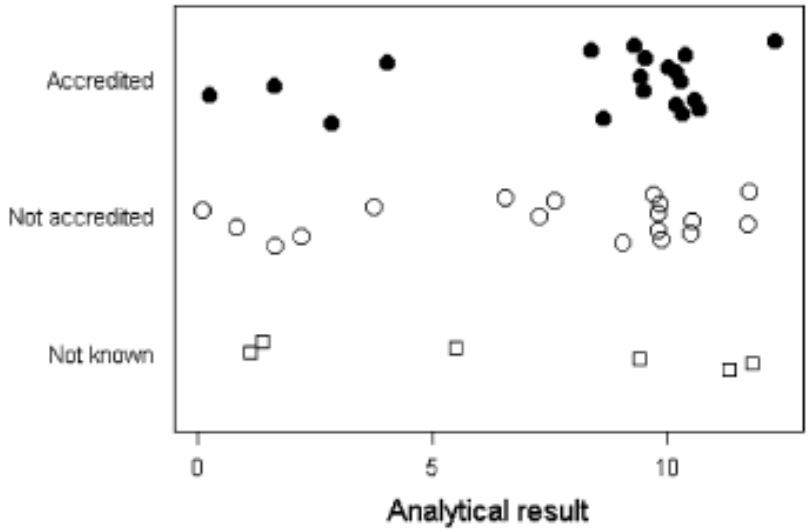


Performance of "accredited" vs. "non-accredited" laboratories for the measurement of trace Cd in water

"There seems to be no evidence that accreditation for this type of analysis of elements in this type of matrix ensures good performance."

Papadakis I, Nørgaard JV, Vendelbo E, Van Nevel L, Taylor PD. 2001. International Measurement Evaluation Programme: IMEP-9, trace elements in water. *Analyst 126:228-33*

Yet another, but with a twist



A comparison of distributions obtained in one study of arsenic (ppm mass fraction).

Among “inliers” (data excluding outliers) “accreditation has no effect on performance”

Among outliers “proportion of outliers is about twice as high for non-accredited group”

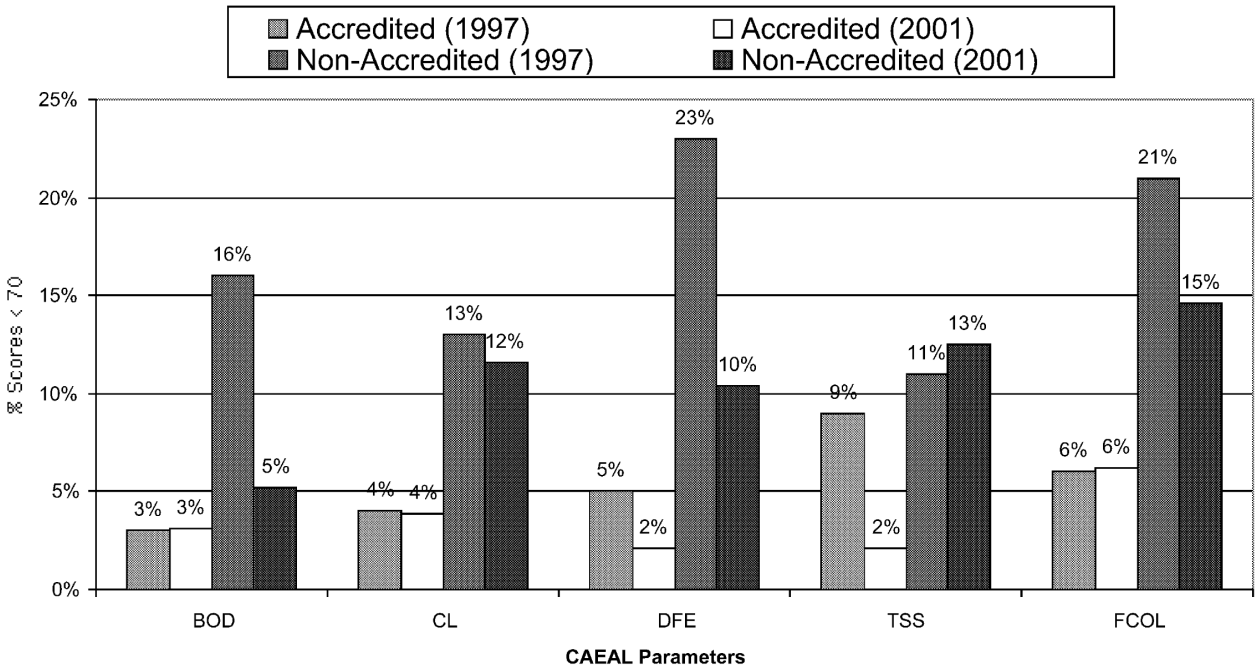
Thompson et al. (2009) Accred. Qual. Assur. 14, 73-78 (Figure 1).

Kind of Supporting Accreditation

- ‘‘*Do fewer PT failures, fewer inspection deficiencies, and a very limited number of government sanctions mean that the quality of patient test results has improved?*’’
- *“*Intuitively we all believe that adhering to the CLIA’88-mandated, good laboratory practices and passing PT improves laboratory test quality.”
- “The indicators assessed in this study generally support this conclusion. However, the direct link between regulatory compliance and quality test results is difficult to prove.”
- “The *success of PT* as a quality tool has been demonstrated by over 50 years of experience.”
- “While our overall assessment is that compliance to CLIA’88, has improved US clinical laboratory performance, we as scientists must distinguish what we know from what we think (assume) we know.”

Ehrmeyer SS, Laessig RH. 2004. Has compliance with CLIA requirements really improved quality in US clinical laboratories? *Clinica Chimica Acta 346:37-43*

Strongly Supporting



Comparison of unsatisfactory scores, 1997 and 2001

Comparison accredited and non-accredited labs of mean scores 1997 and 2001 for 5 measurement parameters (passing is > 70).

Scores are derived from z-scores.

Morris and Macey (2004) Accred. Qual. Assur., 9, 52-54.

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Literature Review Conclusions

- Very mixed
- Overall most find small or no positive effect
  - King et al. (1999) Accred. Qual. Assur. 4, 280-291.
  - Ornemark et al. (1999) Accred. Qual. Assur. 4, 463-472.
  - Papadakis I, et al. (2001) *Analyst 126:228-33*
  - Ehrmeyer SS, Laessig RH. (2004) *Clinica Chimica Acta 346:37-43*
  - Siloaho et al. (2006) Accred. Qual. Assur., 11, 238-245.
  - Thompson et al. (2009) Accred. Qual. Assur. 14, 73-78.
  - Some show difference in the bread of variation among labs (more outliers)
- One finds strong positive effect
  - Morris and Macey (2004) Accred. Qual. Assur., 9, 52-54.

Accreditation

- Positive Effects
  - Management & Technical Functions Defined
  - Guidance/Education for Lab Processes
- Leads people to assume accreditation is an indicator of good results
- Instead, Accreditation appears to give assurance that:

"a quality and organizational system are implemented, so that the service to the client and the ***organizational performance*** (existence of organized records, contract review, fulfilment of deadlines, etc.) are satisfactory in day-to-day work."

- Cortez et al. (2003) Accred. Qual. Assur. 8, 511-513.

Caveats & Questions

- There are many possible causes for the apparent failings of accreditation, some published in the above cited literature.
- Proficiency Testing and Accreditation are often confounding factors that are hard to separate
- Literature searches can be incomplete
- We should consider more research into the efficacy of measurement approaches (interlab comparison, PT, control systems, reference materials, …) versus or in combination with accreditation's process approach.

Possible Reasons: Human Factors

- Negative Factors – Driving to Weak Accreditation Implementation
  - Community is small – many personal relationships
    - Auditing is a person-to-person experience
  - Competitive – if one is too hard, go to another
  - Losing accreditation has many repercussions
    - Bad press, loss of reputation, loss of income, out-of-business
  - Labs pay salary of accreditors
  - Similar to grade inflation
    - Lake Wobegan Children … it is easier if everyone is above average

Note that some of these drivers can be similar for PT

Suggestions for Improvement

- Shift emphasis in accreditation
  - From management process to more performance measurement
  - From "designation" to "demonstration" of measurement competence
    - De Bièvre P, Taylor PD. 2000. "Demonstration" vs."designation" of measurement competence: the need to link accreditation to metrology. *Fresenius' journal of analytical chemistry 368:567-73*
- Increase and report interlab comparisons and other salient measurements
  - PT, reference materials, controls, informal, etc.
  - Would need independent analysis
- Try to counter human factors
- Study the relative merits and impact of performance requirements compared to process requirements
  - What works best

Conclusion & Questions

- We are investing considerable efforts & resources into accreditation
- Is this the most efficient or accurate way to assure performance of forensic laboratories?
- Should we be trying more proven performance based measures, rather than accreditation's process based approach?
- Should we refocus accreditation more towards measurement?
- What should we do about the literature results?