

# The IVD Directive and CE marking

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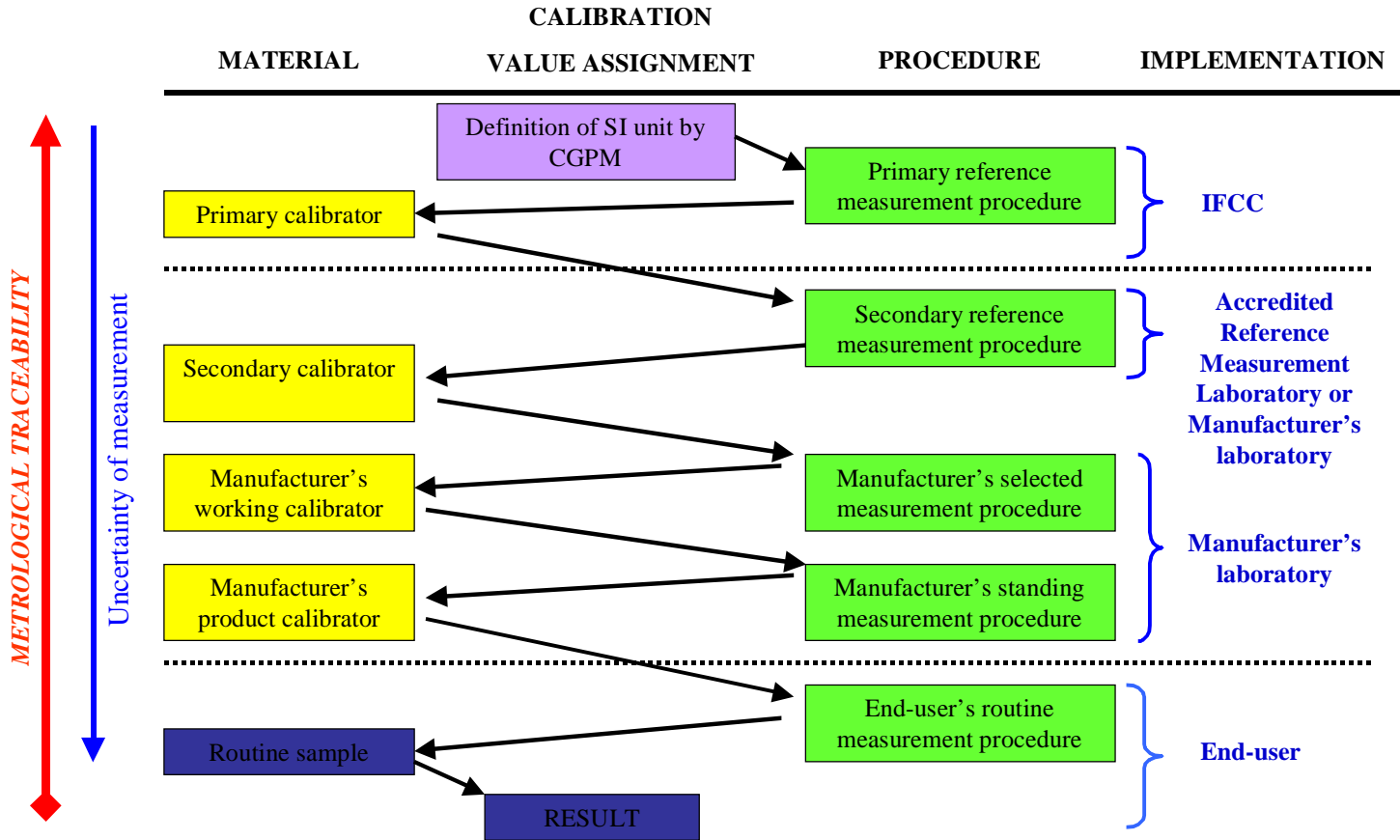
## users' perspective

IEQAS 12<sup>th</sup> Participants' Conference 14/10/2004

## Questionnaire to IEQAS participants — what issues/problems have they seen?

1. Manufacturers' withdrawal of kits?
2. Effect of traceability requirement — any “shifts” in results?
3. Any problems due adjusting/modifying analytical systems, including use of one manufacturer's reagents on another manufacturer's analyser?
4. Other issues?

*(we didn't ask about the perceived benefits!)*



## Summary of responses:

16 labs responded (+2)

10 had experienced kit/reagent withdrawals (some more than one instance)

6 had noticed shifts in values

Adjusting/modifying systems and use of reagents on another manufacturer's system: situation not clear — needs discussion

### Other:

- Some labs use “fudge factor” to align with EQA results — ??traceability
- Use of third party controls
- Difficulty in getting CE marked reagents for Transfusion from UK
- Withdrawal of kits increases need for in-house assays — ?implications