

Accreditation in Irish Medical Laboratories - the current position

Dr Peter Kelly

Chairman, Joint Working Group on Medical Laboratory
Accreditation



Joint Working Group on Medical Laboratory Accreditation.

- Association of Clinical Biochemists of Ireland
- Academy of Medical Laboratory Sciences
- Faculty of Pathologists, Royal College of Physicians of Ireland

Meeting with NAB (5/98)

- Informal exchange of views
- They also emphasised an “independent / third party” process
- Said they were already involved in certification of food laboratories and of one private medical laboratory - notable that they certified **tests** and not the lab
- Nothing to suggest that would accept an Irish “CPA” as equal partners for accrediting medical laboratories
- However, also agreed to inform themselves about the relationship between UKAS and CPA

Current Position (10/11/98)

- Still in Discussion with Department of Health - no definitive ruling
- Many Labs preparing for CPA Accreditation
- One Commercial Lab has NAB Certification of a small Range of “Tests”



What's happened since then.....?

- INAB
- DOHC
- HSE
- ISHAB
- The Standards
- The Laboratories
- CPA
- Statutory/Legal Status
- Europe
- Recent JWG developments



INAB

- Following exploratory meetings the JWG put formal proposals in writing to INAB. Discussions facilitated by DoHC
- Proposals included:
 - 3 representatives of JWG on Board
 - Sectoral Committee composed largely of profession and nominated by JWG or parent bodies. Would have its own logo etc
 - Accreditation to evolving ISO15189.....



.....INAB

After initial promise talks broke down as INAB appeared to resile from its initial constructive stance to unwillingness to give ground on any major point.

More on INAB later.....



DoHC

Initially very helpful as honest broker between JWG and INAB.
Appeared informed and committed.

Following breakdown of negotiations with INAB, seemed to
“lose interest”. Regular changes of personnel. Newer people
poorly informed about lab accreditation.

Coincident establishment of IHSAB. Did they feel that lab
accreditation could be parked in IHSAB?

With the establishment of HSE and IHSAB, DoHC becoming
increasingly irrelevant to the process.



HSE

Apart from the Blood Directive we do not know what the attitude of the HSE to laboratory accreditation is.

General impression that they regard it as the business of IHSAB.

HSE will nevertheless be of crucial importance when it comes to proper funding of accreditation



IHSAB

Accredits hospitals to a home-grown standard based on Canadian (CCHSA) standard.

Labs visited in course of inspection visit; no in-depth examination.

IHSAB “recommends” INAB for laboratory accreditation - on what authority?

Primary duty of accrediting body is to consult with sectoral interest/expert groups!



The Standards

- ISO 15189. Now formally adopted by ISO. Accepted by INAB as a basis for medical laboratory accreditation. 2nd edition under deliberation.
- CPA: new (2nd edition, 2004) standards incorporate ISO15189, 17925, 9001:2000 and EC4 Essential Criteria



Survey of Irish Laboratories on Accreditation Status 4/04

Type of lab	Responded
Public Hospital	29*
Private Hospital	7*
Private Laboratory	1
Research Laboratory	1
Blood Culture	1
Reference Laboratory	1

No of questionnaires issued: No returned: (50 representing 40 institutions)

*36 of 51 hospital laboratories responded.



Survey of Irish Laboratories

	Accredited	Preparing	Total
CPA	5+2	22	29
JCI (?)	2	1	3
INAB	2 (+6 food labs)	1	3+6
IMB	1	0	1
EFI	1	0	1
Undecided	N/A	1	1
Not preparing	N/A	18	18
Total	11+6	24+19	

Conclusion

Majority of Irish Hospital Laboratories: (i) are actively involved in Accreditation
(ii) favour CPA Accreditation (by a wide margin).



CPA

- Many Irish labs accredited or registered with CPA
- CPA standards, according to them, encompass ISOs 15189, 17025 and 9001:2000, as well as EC4 Essential Criteria
- CPA overworked and short of assessors \therefore reluctant to take on new labs in Ireland (? discouraged by INAB under MLA)
- Committed to continue with existing clients
- Would welcome cadre of Irish professionals for training as assessors
- Joint assessment with UKAS in 2007 expected to bring CPA under the EA aegis with international recognition



Statutory / Legal Status

- With the exception of Blood Laboratories, accreditation is not a legal requirement for medical laboratories.
- Blood Labs must be accredited following Blood Directive
- In Ireland - accreditation to ISO15189 + additions on traceability etc. required
- Accrediting body not specified. Most assume it should be INAB - why?
- EU competition legislation suggests that we are entitled to seek accreditation from any competent body in EU
- If CPA accredits to ISO15189, can they accredit Irish Blood Labs?



Europe

- EA (European Cooperation on Accreditation) set up a Healthcare Subcommittee late 1998 best thought of as a sectoral advisory committee
- INAB and UKAS are both affiliates
- PK a representative of Medical Profession through UEMS Board of Pathology
- Not representative: lab professionals in minority
- Initial reluctance to adopt ISO15189 and still some resistance to it
- Tends to view 15189 as a modification of 17025 with consequent problems *especially in the interpretation of scope - tests vs competences*
- Discontent among lab professionals has lead to a recent meeting between EC4 and delegation of EA



JWG - recent developments

- Following breakdown of talks with INAB - “drift”; some seeming to favour INAB, others strongly committed to CPA
- Meeting with Board of CPA - cordial but inconclusive. CPA could not commit unconditionally to Ireland; would welcome assessors
- Joint meeting of Presidents, Dean and JWG to get back on tracks successful. Confirmed commitment to CPA but to continue to investigate possibilities with INAB ?with CPA as co-player
- Exploratory meeting with INAB 7/05. Outcome - JWG to submit draft proposal to INAB for consideration by their board



JWG Proposal to Board of INAB

- What we want:
 - A system of accreditation which maintains the ethos of peer review without compromising independence
 - Smooth transition from CPA to INAB
 - Control of fees eg: through use of voluntary assessors
- What they get:
 - INAB would be the recognised accrediting body for Irish medical labs
 - Structures would allow INAB to cope with the huge increase in workload consequent upon extending into the medical laboratory sector



JWG Proposal to Board of INAB - 2

- Peer-to-peer relationship between JWG and INAB similar to CPA-UKAS
- Joint approach to CPA to devise a protocol for accreditation using joint assessors
- New Irish assessors to be trained by CPA and INAB
- Sectoral committee: strong representation from JWG, appointed by INAB on recommendation of JWG
- Board representation of sector: 3 members, one from each constituent group of JWG
- Fees to be closer to CPA than INAB through use of voluntary assessors

Have you seen anything like this before?



Meeting of JWG with INAB 9/06

- Cordial and constructive
- Proposals had been discussed by Board and agreed that they would be a basis for further discussions
- CPA (subject to their agreement!) would be involved in some way, at least initially.
- Next move:
 - “sound out” CPA
 - Clarify our own thoughts about how they might remain involved
- Further meetings planned



How can CPA fit into future structures?

- Retain status quo?
 - Assumes CPA is willing/able to continue
 - Risk of statutory/regulatory prescription
- CPA (Ireland)? in collaboration with INAB
- CPA assessors with INAB - but they use two different standards
- CPA trains Irish assessors for INAB - see above
- **Any suggestions?**