

Guidance on Consultants Contracts for ISO15189 laboratories and assessors

GD01

The Irish National Accreditation Board (INAB) is the national body responsible for the accreditation of medical testing laboratories to ISO 15189 (Medical Laboratories - Particular requirements for quality and competence). This international standard requires that the interpretation of the results of examinations, and relevant clinical advisory services be provided by appropriate laboratory professional staff.

The standard also specifies that the laboratory will be directed by a person or persons having executive responsibility and the competence to assume responsibility for the service provided. A Medical Consultant (for a specific discipline and listed on the Specialist Register) is deemed by national regulations, and by INAB policy as the appropriate professional staff, to fulfil these requirements. INAB accepts the position of Consultant Clinical Biochemist in the discipline of Clinical Biochemistry/Chemical Pathology. These criteria apply to deputy positions also.

In performing INAB assessments to this standard, in the private hospital sector, INAB satisfies itself that appropriate contractual and indemnity arrangements are in place, particularly for medically qualified personnel providing clinical advisory services on a private basis.

In HSE funded hospitals where the consultant post has been approved, a standard HSE contract will be available. Deputy arrangements may be provided on a private basis and contractual arrangements will need to be in place and assessed.

In HSE funded hospitals, where the consultant post has not been approved or sought, is pending or indeed refused by the HSE, then the INAB Board and legal advice have confirmed the following equivalence approach is to be adopted:

Ascertain the status of HSE approval from hospital managers and the consequent nature of the contracts employed for medical consultant staff. A letter sent from INAB in September 2011 to all managers of HSE funded hospitals advised of same and PS10 has been amended;

- For those situations where approval is NOT in place OR is pending OR has been refused, the hospital is responsible for deciding whether to enter into private contractual arrangements.
- It is the responsibility of the hospital to satisfy itself as to the legality or otherwise of any contract presented taking into account all applicable employer obligations and policies and their responsibility to demonstrate conformance to ISO 15189 and INAB requirements for their accreditation application.

- Where a hospital elects to enter into these private contractual arrangements in the absence of HSE post approval, then the INAB assessment team will review the private contract arrangement with particular focus on indemnity for the scope of activities relevant to accreditation (INAB has received advice that the HSE does not provide indemnity cover in situations where post approval is not in place and so this must be privately undertaken), qualification/competence criteria as specified by the hospital and the scope of consultant duties;
- In these instances, the hospital and not the HSE is the direct employer and as such all contracts must be signed by the hospital manager;
- Where the terms of a contract are not clearly and readily understood (either through presenting an addendum contract or any other variation of a standard HSE contract template) the hospital laboratory will provide, where requested, independent legal opinion as to the validity and legality of said contract.

General Matters Expected to be addressed in a Contract:

- Parties to the agreement and purpose;
- Term of the agreement and conditions of termination;
- Duties & obligations of the contracted party i.e. consultant, and recourse open to contractor for failure to comply with terms of contract;
- Status of contract - is it employer/employee or contractor/sub-contractor relationship;
- Fee;
- Exclusivity - is the contracted person (consultant) available to work elsewhere;
- Insurance and indemnity cover clearly stating who is responsible for it and its extent;
- Confidentiality.

For further information about this statement please contact an INAB officer at The Irish National Accreditation Board.

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