



The Royal College of Pathologists

Pathology: the science behind the cure

## Guidance

### Assessment of competence against the ISO 15189:2012 standard

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## **1 Background**

- 1.1** The College has become aware of instances where UKAS assessors, in assessing laboratory processes against the ISO 15189:2012 standard, have demanded various forms of evidence that the laboratory is assuring that its pathologists are competent to do the work they undertake. The precise demands have varied but they have included duplication of the requirements of medical appraisal and revalidation and disclosure of confidential personal reports from interpretive EQA schemes.
- 1.2** Accreditation to the ISO 15189 standard requires the laboratory to state how it ensures the ongoing competence of its staff. UKAS assessors may legitimately request evidence that the stated processes are being followed. Peer assessors should follow guidance from professional organisations in considering whether or not a laboratory conforms to currently accepted practice.

## **2 Access to information generated through appraisal and revalidation**

- 2.1** The College view is that with the introduction of medical revalidation by the GMC, the UK has arguably the most comprehensive system in the world for the assurance of the ongoing competence of its doctors. The competence of each doctor is assessed against his or her stated 'scope of work'. Compliance with that system has statutory force. Repeating the process as part of medical laboratory accreditation is unnecessary.
- 2.2** In accordance with national agreements, medical appraisal records are confidential between the doctor, the appraiser and the Responsible Officer. UKAS assessors should seek assurance that all medically qualified pathologists are complying with this system and that the Responsible Officer is thereby assured of their fitness to practise. If a doctor has maintained a licence to practise, and is therefore regarded by the GMC as competent to undertake medical practice as set out in his/her scope of work, that fact is published by the GMC on the List of Registered Medical Practitioners available online. Further information on a doctor's revalidation status, if needed, should be available from the Responsible Officer.
- 2.3** Local managers are not entitled to view medical appraisal records or to ask appraisers to divulge confidential appraisal information. They cannot claim that access to such records is part of their local quality assurance process. As a result, UKAS assessors should not request to see such confidential information.
- 2.4** Suggestions that appraisal records may be viewed with the consent of the appraisee raise concerns about the validity of that consent if there is any element of duress. If a doctor is told that disclosure is necessary or his/her laboratory will fail to achieve accreditation that constitutes duress.
- 2.5** Laboratories will also wish to assure staff competence by other means, such as incident reporting, monitoring of amended reports and audit. These additional approaches should not require the release of confidential appraisal information.
- 2.6** The College is aware that non-medical clinical scientists and oral pathologists registered by the General Dental Council are not currently subject to a similar revalidation process, and is of the opinion that this is an omission; all consultant-grade staff should be subject to a similar process to ensure their ongoing fitness to practise. In the absence of a national revalidation system for non-medical staff, the College recommends that clinical scientists and oral pathologists should be subject to a local system of annual appraisal which, as far as is practicable, parallels the GMC approach, and that evidence of compliance with such a system should satisfy UKAS assessors in respect of the competence of these professional groups.

### **3 Interpretive EQA and personal performance**

- 3.1** Participation in interpretive EQA schemes is a valuable educational activity and should inform the annual appraisal discussion, but these schemes are not designed to have the rigour of a professional examination and should not be relied upon as evidence of competence. Participation in such schemes might be a local management requirement, but reports generated are confidential. As with confidential appraisal records, access to detailed interpretive EQA reports cannot be cited by local managers as a routine method for assuring professional competence. There can therefore be no justification for UKAS assessors demanding to see such records.

### **4 Pathologists providing second opinions on complex cases**

- 4.1** The College has also been informed of UKAS assessors asking for documentary evidence that pathologists from whom a second opinion is sought have the proficiency required to offer that opinion. This could potentially inhibit requests for second opinions and effectively prohibit the sourcing of second opinions from outside the UK.
- 4.2** The ISO 15189 standard includes several statements on referral laboratories, the most relevant of which in this context is clause 4.5.1: *“The laboratory shall have a documented procedure for selecting and evaluating referral laboratories and consultants who provide opinions as well as interpretation for complex testing in any discipline”*.
- 4.3** The College believes that it is important to distinguish between a second opinion (where the second opinion is sent to the requesting (primary) pathologist and responsibility remains with the primary pathologist) and referral elsewhere for analysis (as is common with unusual biochemical assays or genomic analyses) where the responsibility for the result is transferred wholly to another person or laboratory.
- 4.4** When a sample is referred for analysis, with transfer of responsibility, it is entirely appropriate for UKAS assessors to ask how the competence of the external agency is assured.
- 4.5** However, when a second opinion is requested, the requesting (primary) pathologist retains responsibility for all professional judgements on how to investigate the sample – including whose opinion to ask, and how to use that opinion. In that situation the ‘documented procedure’ mentioned in the ISO 15189 standard could be that the primary pathologist is expected to use his or her professional judgement to identify an appropriate person to ask for a second opinion. In that situation it is not appropriate for UKAS assessors to question the professional judgement of the person from whom an opinion is sought.

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