The Royal College of Pathologists
Pathology: the science behind the cure

Principles and guidance for interpretive external quality assessment schemes in laboratory medicine

October 2017

Author: Professor Peter Furness, Director of Professional Standards

Unique document number	G153
Document name	Principles and guidance for interpretive external quality assessment schemes in laboratory medicine
Version number	1
Produced by	Professional Standards Department
Date active	13 October 2017
Date for review	13 October 2022
Comments	In accordance with the College's pre-publications policy, this document was on The Royal College of Pathologists' website for consultation from 18 July to 18 August 2017. **Dr Lorna Williamson** **Director of Publishing and Engagement**

The Royal College of Pathologists
4th Floor, 21 Prescot Street, London, E1 8BB
Tel: 020 7451 6700, Web: www.rcpath.org
Registered charity in England and Wales, no. 261035

Contents

1 Scope of this guidance

This guidance relates only to external quality assessment (EQA) schemes where the participant is an individual pathologist, not a whole department, and where the participant is expected to make a professional judgement about the meaning or significance of the material circulated, rather than making a measurement. Compliance with this guidance is a requirement for any such scheme that wishes to obtain approval from the RCPath Interpretive EQA Steering Committee as a scheme suitable to provide input to medical appraisal and revalidation.

Schemes currently exist which ask for professional judgement from a laboratory rather than from an identifiable individual; or where no attempt is made to feed back an objective report on personal performance. Such schemes are outside the remit of this document.

The College regards the feedback that participants gain from appropriate interpretive EQA schemes to be an important contribution to annual appraisal and medical revalidation. Reference should be made to the College's guidance on supporting information for medical appraisal for pathologists (available from the College website). Schemes that comply with this guidance and have obtained approval from the College's Interpretive EQA Steering Committee may be regarded as being suitable for that purpose.

However, interpretive EQA schemes are not normally designed to have the rigour of a professional examination and therefore the results should NOT be regarded as a form of proficiency testing that provides a measure of a pathologist's competence.

Some schemes combine evaluation of technical/laboratory performance and the performance of individual pathologists. Such schemes vary in their approach and some are under development. It has not proved possible to devise guidance that covers such diverse activity. Those schemes are invited to regard those aspects of their work that relate to the performance of individual pathologists as being within the remit of this guidance and to consult with the Steering Committee to discuss whether and how College oversight of their work can be delivered.

The current updating of the principles and guidance for interpretive EQA schemes in laboratory medicine incorporates the recommendations in the Pathology Quality Assurance Review, published in January 2014, relating to individual performance. These five points listed on page 23 of that Review include the leadership role of the Royal College of Pathologists, the inclusion of the performance in individual schemes within the appraisal structure, the support for any necessary remedial action by the employing organisation, and the resourcing of individual participation by the employing organisation.

This document refers to iEQA participants as 'pathologists'. This should not be taken to exclude non-medical staff who have final responsibility for issuing interpretive reports, nor should it be taken to exclude such staff who are not members of the RCPath.

2 Benefits of interpretive EQA schemes

An effective interpretive EQA scheme provides a structure that supports professional standards in interpretive aspects of pathology:

- to standardise and harmonise diagnostic criteria across the country or region
- to keep members abreast of developments in the specialty
- to form part of a framework for high-quality, relevant and effective continuing professional development (CPD)

- to avoid professional isolation
- to empower a participant to reflect on their performance and take corrective action as required, therefore improving patient safety
- to input into accreditation of laboratories – there is a mechanism in place to provide external triangulation during appraisal
- to provide a safe environment for the organiser to raise concerns regarding possible sub-standard performance of a participant to an appropriate professional standards body for further investigation.

The College provides ongoing support for organisers of interpretive EQA schemes by the production of principles for scheme management and operation (below) and governance support.

3 Arrangements for interpretive EQA schemes

This guidance describes the organisation and operation of interpretive EQA schemes. It is based on the arrangements in the College's original guidance from 1998 and how schemes have evolved since. It is not intended to parallel or duplicate the ISO17043:2010 standard (*General requirements of proficiency testing*). The College will approve schemes that submit standard operating procedures (SOPs) and annual reports that demonstrate compliance with its guidance; the additional role of accreditation is to verify that schemes are operating in accordance with their SOPs. It has been observed that very small schemes may have difficulty in complying with the implementation of this International Organisation for Standardisation (ISO) standard, not least because their small size makes some requirements, such as the appointment of a quality manager, impractical. Furthermore, it has been observed that schemes can gain accreditation under that ISO standard without having any element of assessment of personal performance that feeds into the medical appraisal and revalidation process managed by the General Medical Council (GMC). As a result, the aims of this guidance and the ISO standard differ. Schemes may therefore seek to comply with this guidance, the ISO standard, or both, depending on the nature of the scheme.

4 Scheme organisation

4.1 Legal entity

Legal accountability must be agreed by means of a contract or agreement with either the organiser's employer or the host organisation of the scheme.

4.2 Organiser

The general running of the scheme should be the responsibility of one individual, referred to as the organiser. The organiser may also be a participant in the scheme; if so, mechanisms must be defined and applied to allow the organiser to participate without advantage.

Any arrangement for remuneration of the organiser's time must be defined as part of the scheme's SOPs and, if appropriate, in a contract with the organiser's employer.

The organiser will normally be a pathologist with experience of the area of practice involved, but need not be regarded as an expert, because the organiser should not be asked to exercise judgement in the interpretation of the cases used in the scheme.

Permission to be organiser of the scheme should be obtained from the organiser's main employer. The role should be reviewed during annual appraisal.

4.3 Other personnel

Additional personnel should be contracted to assist with management and operation of the scheme. This may be on a full-time or part-time basis.

4.4 Governance

Host organisation

A host organisation, where it exists, will have its own arrangements and requirements for scheme governance; these should be agreed, specified in writing and complied with. Where the host organisation manages the financial accounts of the scheme, it will be necessary to comply with that organisation's financial and accounting arrangements. Reasonable charges may be levied by the host for services provided. However, the host organisation should not seek to make a profit from the existence of the scheme.

Organising committee

Where personnel contracted by the scheme consist of more than an organiser and a secretary, formation of an organising committee should be considered. This group should advise the organiser on the design, planning and operation of the scheme. Terms of reference should be defined and examined by the RCPath Interpretive EQA Steering Committee.

RCPath Interpretive EQA Steering Committee

The College shall maintain an Interpretive EQA Steering Committee, subject to its agreed terms of reference, with oversight by and annual reporting to College Council. This committee will take responsibility for assisting and advising interpretive scheme organisers on how their schemes should function and for checking that a scheme's SOPs comply with this College guidance.

The RCPath Interpretive EQA Steering Committee shall have the power to grant or withdraw College approval for an interpretive EQA scheme, based on the scheme's SOPs (together with the explicit assurance of the scheme organiser, any reports from its participants and any other material that the Steering Committee deems relevant) confirming compliance with the guidance in this document and thereby the relevance of the approved schemes to medical education, appraisal and revalidation. It shall maintain a list of College-approved interpretive EQA schemes and contact details for scheme organisers on the College website, so that pathologists and their appraisers can identify schemes appropriate to their clinical practice.

Scheme organisers will submit a structured annual report to the Steering Committee, so that the College maintains a record of continuing operation of all registered schemes and can decide on an annual basis whether a scheme continues to satisfy the criteria for approval. Annual reports to the Steering Committee should include ISO17043 accreditation status, subscription fee per person, new developments, problems and details of each round conducted in the year, including participation rates, numbers of cases circulated, incidences of sub-standard performance and how they were managed.

The Steering Committee will provide a route by which participants can address unresolved complaints about how an interpretive EQA scheme is being run.

If a scheme organiser wishes to appeal against a decision not to approve a scheme, this should be done in writing via the President to College Council.

The Steering Committee should consider running an annual educational meeting for scheme organisers to discuss problems, solutions and innovations in running interpretive EQA schemes and to provide training and support for new interpretive EQA scheme organisers.

Funding for the Steering Committee and associated administrative support by the College should be generated by an annual levy on all approved interpretive EQA schemes and a fee for considering applications for recognition from non-approved interpretive EQA schemes.

College Professional Performance Panel
Where scheme organisers need to take action in respect of the performance of an individual pathologist (discussed below), they are expressing a legitimate concern about that individual pathologist (who in most cases will be a Fellow of the College). But they are very unlikely to have **proof** that a problem exists. The appropriate body to consider questions of competence of individual pathologists is the College's Professional Performance Panel. This panel is chaired by the College President, who may delegate further investigation of individual cases to the Director of Professional Standards or to another senior pathologist with an appropriate understanding of professional standards in the specialty involved. It should be stressed that in this context the Professional Performance Panel will not normally attempt to impose sanctions on the pathologist; rather, its action, if a credible explanation for the low interpretive EQA scores is not forthcoming, would be to report the problem to the appropriate authority (normally the participant's responsible officer) for further investigation and decisions about any action needed to protect patient safety.

Feedback from participants and users
There should be a mechanism for participants to make suggestions regarding scheme operation. This may be via an advisory panel, formed of representatives of the full participant membership, or via a full group meeting, or both. Other feedback mechanisms such as user surveys may also be appropriate.

A scheme advisory panel may be set up, made up of representatives from the participants, whose main function is to advise the organiser on aspects of the scheme and to represent the participants' views. This panel has an advisory role only and the organiser will make the final decision over scheme design and operation. The mechanism for appointing any such advisory group should be defined and membership should be open to all eligible participants.

4.5 Business continuity

Mechanisms should be in place for assuring continuity of the scheme in the event of change or absence of key personnel or change of host organisation. Processes for recruiting and replacing the organiser, including triggers for replacement, and other key staff should be described.

Deputies should be assigned to take over key roles in the event of long-term absence.

Mechanisms for transfer of scheme funds and assets to a new host organisation should be described.

4.6 Confidentiality

Systems will be developed to ensure that confidentiality of participants is maintained throughout the scheme. This includes submission of responses, results analysis, participant responses and communication between participants and organiser.

The scheme should have defined mechanisms for non-submission or removal of patient identifiers and location identifiers from all circulated case material that complies with the Data Protection Act 1998 and the Caldicott principles.[1]

Schemes should have some form of confidential coding of participants, so that reports of personal performance may be transmitted securely and in a confidential manner, preferably with the link between participant code and participant identity **not** being known to the scheme organiser. The key linking codes to participants' names may be held by one person, usually a

[1] As originally described at http://webarchive.nationalarchives.gov.uk/20130107105354/http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4068403 and subsequently updated – see https://en.wikipedia.org/wiki/Caldicott_Report

[2] This superficially counterintuitive conclusion is easily justified. In a difficult cellular pathology case, failing

secretary (usually referred to as “the EQA secretary”), whose role in the scheme includes putting numbered letters and reports into correctly addressed envelopes (or adding file attachments to secure emails). Alternatively, if facilities exist, participants may be invited to use a personal user name and password to log in to a secure website to submit responses and retrieve their results. By such methods, scheme organisers can be kept unaware of the performance of all participants except for their own. This method can also be used if it is necessary for the organiser to send messages to participants discussing their personal performance. The EQA secretary addressing such messages also can be kept unaware of the contents. Records of participants’ results and any communication should be maintained by the secretary for at least five years, corresponding to the revalidation cycle of the scheme members.

4.7 Documented procedures

The scheme must have written documentation of its SOPs, describing the scheme management and operation as outlined in these principles. SOPs, including new revisions, must be submitted to the RCPath Interpretive EQA Steering Committee for approval, to assure continuing compliance with these principles.

The SOPs should make explicit how the principles in this document are met. Document control mechanisms should be in place.

A generic SOP template should be maintained by the Steering Committee and scheme SOPs submitted to the College for approval should include the items listed in this template.

All participants of the interpretive EQA scheme must be given access to and must agree to conform to the SOPs.

4.8 Scope of the scheme

The repertoire of the scheme should be defined.

The scheme must have a clear definition of who is eligible to participate. This will normally be limited to practitioners who are authorised to undertake independent practice in the relevant specialty in the UK. If others (such as trainees) are allowed to participate, they must be identified in a way that allows the organiser to analyse individual results separately, so that sub-standard performance by an independent practitioner cannot be masked by the expected lower performance of trainees. Qualifications and experience for membership should be stated. For specialist schemes, the definition of a specialist should be stated.

When using the responses of participants to determine the ‘correct’ response for each case, mechanisms should be in place to ensure the expertise is not diluted by less experienced members, such as trainees or non-specialists.

Where a scheme has participants who work outside the UK, an explicit decision must be made on whether or not those overseas participants contribute to the definition of an acceptable response. That decision must be justified to and accepted by the Steering Committee. Overseas members may need to be scored in a separate cohort. Mechanisms for reporting sub-standard performance to relevant professional bodies would then need to be defined.

4.9 Complaints and appeals

There must be a defined mechanism by which participants can pursue complaints about the way in which the scheme is run or to raise an appeal against their personal assessment.

If a complaint cannot be resolved by the scheme organiser to the satisfaction of the complainant, there must be a defined process of escalation. This may include local

processes, but ultimately it should be possible for the complainant to submit the complaint to the Steering Committee.

4.10 Funding

Running an interpretive EQA scheme requires financial support to pay for staffing costs: the organiser's time, secretarial support, quality management, and to provide infrastructure facilities. These include computing, specimen preparation, digital imaging, website, printing and photocopying facilities, and postage, office and finance facilities.

Schemes should be funded to cover all relevant costs on a non profit-making basis by subscriptions from participants or their employers. However, expenses may not be uniform in each year. A surplus in one year may be permitted, if this is to be allocated to a known expense or development of the scheme (e.g. investment in new technology or equipment) in a subsequent year.

Where participation is required by an employer, the employer should pay or reimburse the full cost of participation. The scheme may choose to have differential subscriptions for different cohorts of participants (e.g. cheaper for trainees and junior staff), but overall must not make a profit.

Mechanisms and responsibilities for invoicing, recovery of debts, purchasing and budget review should be defined and agreed with the host organisation by means of a service level agreement or contract.

Costs and charges should be reviewed annually. Accounts should be presented to participants annually.

5 Scheme operation

5.1 Information for participants

Mechanisms for joining the scheme should be made available to potential participants.

It is a responsibility of the scheme organiser to make all relevant written information about the scheme available to participants when they join the scheme and whenever changes are made.

5.2 Scheme design

The scope of the scheme, including repertoire, number of cases and the frequency of circulations, should be decided by the organiser or organising committee, subject to agreement by the Steering Committee via submitted SOPs. More cases will increase the educational benefit but this has to be balanced against the time and resources required.

Obtaining case material

The scheme should have a defined mechanism for obtaining and validating cases, such that the full repertoire of the scheme is covered (either in every circulation or in rotation) in accordance with the scheme design.

There must be defined processes for assessing the quality of the case material. If the case is accepted despite variation in the material provided to different participants, the effect of any variation should be considered when assessing participant responses. If the quality of the material is checked by the organiser, the organiser should be unaware of the original diagnosis if the organiser needs to participate in the scheme on an equal basis to the other members.

The material used in the scheme should be selected by a clearly defined method that is understood by the participants, such that the cases chosen have relevance to a participant's routine workload.

Cases for personal assessment (as distinct from "educational cases", see below) should be contributed by the participants, following agreed guidelines. They should be actual cases experienced by the participants, not invented "examination questions". Cases may be submitted by a subgroup of participants, as long as membership of the subgroup is open to all participants and there is no selection process based on any concept or assessment of expertise in the field. Cases must not be all selected by one person.

Extremely simple cases should be avoided, because cases with 100% correct responses take up participants' time but provide little educational benefit and no evaluation of participant performance. On the other hand, bizarre cases and case report material are not appropriate for the assessment of personal performance. A protocol to achieve this balance must be identified. For example, one suitable method would be to ask all individual participants to contribute cases, in rotation, from those personally reported between specified dates.

The person submitting the case has a responsibility to ensure that the case is suitable for the scheme.

Since the intention is to mimic cases that form part of the diagnostic workload, relevant information that was available when the initial evaluation or report was formulated should not be withheld without good justification. The validity of that justification should be reviewed when the acceptability of the case for personal assessment is reviewed (see below).

The person submitting the case must ensure that the diagnostic requirements of any original biological material (the primary sample) is complete before submission to the scheme. The scheme should have mechanisms in place for the return of any unused original material to the contributor as soon as possible.

If material is in a form that cannot readily be replicated for interpretive EQA purposes then other formats, such as photographs or digital slides of the original preparations, may be made available if that approach has been set out in the approved SOPs.

If the submission of post-mortem material is permitted, compliance with the Human Tissue Act 2004 must be confirmed in writing by the person submitting the material.

Educational cases

Schemes may wish to include a proportion of difficult cases to add interest and to enhance the educational element, but these should be clearly identified as such to the participants and should not be used for subsequent personal performance analysis. For such cases, the scheme's normal case selection criteria may be relaxed.

Choice of method of interpretation

Participants should normally be expected to interpret the case material in a way that is consistent with their normal routine procedures. Where the nature of the case material does not permit this, the scheme should instruct participants to use a specified method in accordance with the design of the scheme.

Where participants choose the method of interpretation, assessment of participants' results should accommodate acceptable variation.

Participant responses

Ideally, responses to schemes should be in a similar format to any relevant routine reports.

Full compliance with this ideal may not be possible, because long textual reports are very difficult to analyse. Where this is not practicable, directions for acceptable responses (e.g. a simple diagnosis or diagnoses) or a proposed course of action or advice should be given.

Free text responses are preferable where routine reports are issued in the form of free text. Multiple choice answers can be justified where there is a relatively short list of possible responses.

If a list of response options is offered to participants but the list has to be adjusted for each case, the scheme is deviating considerably from normal practice and whoever draws up the list of options will not be able to participate in the circulation on an equal basis. Such a

design would therefore need good justification if it is to be accepted by the Steering Committee.

Differential responses should be permitted where the participant has uncertainty in how to respond, but participants must expect such uncertainty to be regarded as a less-than-ideal response if the uncertainty is not shared by colleagues.

The purpose of the scheme is to assess personal ability to make an interpretation, therefore discussion with a colleague prior to result submission is not permitted, even in circumstances where consultation with a colleague would be good practice in a routine workload.

The scheme design may allow participants to opt out of responding to cases in areas that are outside their normal repertoire of work, but any such opt-out should be stated by the participant to the scheme organiser in advance and its existence should be stated on any certificate of participation in the scheme. The number or proportion of such cases should be clearly identifiable from the feedback provided to the participant and should be discussed at the participant's annual appraisal, because a large proportion of 'opted-out' cases may undermine the validity of participation in a scheme.

Failure to provide a response for a case within a single circulation (other than if opting out, as above) should be considered an error.

Individuals may have good reason occasionally to fail to participate in a circulation, such as ill health or annual leave. Failure to participate in a circulation therefore should be omitted from the assessment rather than being recorded as sub-standard performance. However, schemes must have a defined minimum rate of participation and a mechanism for monitoring participation rates of each participant.

Evaluating responses

As the case material circulated requires interpretation, it is likely that there are a variety of possible responses. Mechanisms must be in place for determining the most appropriate (or 'correct') response.

The appropriate response should be defined on the basis of what a group of competent practitioners are able to make of the material that was circulated.

In some circumstances, the correct response therefore might be an admission of uncertainty or a need for further information or testing. Consequently, the method used must not rely on one individual to define what a 'correct' response is, no matter how respected or 'expert' that individual might be. A more appropriate method is to start by considering the consensus of the whole group of participants as expressed in their responses.

If a case is suitable for the evaluation of the performance of individual participants, a response deemed to be appropriate should have been made by a high proportion of eligible participants. Schemes may define what represents 'a high proportion' in their SOPs, subject to agreement by the Steering Committee, but 75% is recommended. This assessment should not include participants who have excluded themselves from an applicable element of the scheme, trainees or any others who for whatever reason might not be expected to attain the level of competence of an independent practitioner in the UK.

Decisions on whether an individual case fulfils the criteria for use in personal assessment, and how such scores or grades should be allocated, should ideally be made by a meeting open to all eligible participants (a participants' meeting) in accordance with an agreed SOP. If a majority opinion is not forthcoming at such a meeting then the case should not be used for personal assessment. Such judgements should not be made by the scheme organiser acting alone.

It is not appropriate to delegate the role of the participants' meeting to a subgroup of participants unless membership of that subgroup is equally open to all eligible scheme participants. These decisions revolve around how an average pathologist should be expected to interpret the material that was circulated. **A subgroup of 'experts', whether self-identified or invited, is therefore not an appropriate decision-making group.**

Similarly, participants who for whatever reason might not be expected to attain the level of competence of an independent practitioner in the UK should not contribute to the decision-making group.

If it proves impractical to organise a quorate participants' meeting, then agreement on assessment criteria can be achieved by online discussion, teleconference or a questionnaire involving a sufficient proportion of members, as defined by the scheme's SOPs.

Where the interpretation given by the original case contributor and the consensus interpretation are not in agreement, mechanisms should be in place for notification to the original contributor advising a review of the patient, if appropriate.

5.3 Providing personal performance feedback

Various methods of identifying the 'quality' of each response are available and this guidance does not prescribe a single approach. The Steering Committee is responsible for advising on appropriate mechanisms. However, the method must:

i) be understood and agreed by the participants

ii) allow each participant to evaluate their performance objectively against the range of performance of the group and identify specific areas of weakness

iii) allow no advantage or disadvantage to any participant in comparison with the whole group

iv) be acceptable to the Steering Committee and the Professional Performance Panel.

Certain important conclusions reached during the early development of interpretive EQA schemes still seem counterintuitive to many pathologists, so the following arguments must be understood:

i) if an erroneous diagnosis is made in an interpretive EQA scheme, its relevance to the performance of the participating pathologist must be assessed by their peers on the basis of the difficulty of the case and the nature of the error. Counterintuitively, **the potential impact of the error on the patient is not relevant.**[2]

ii) the aim is **not** to evaluate whether or not the participant identifies the correct diagnosis. Rather, the question asked should be "What should a competent pathologist make of the material provided?" In some cases, the answer should be a differential diagnosis, or a course of action such as further testing. A single confident diagnosis made on the basis of inadequate information, even if that diagnosis subsequently proves to be correct, might be indicative of an overconfident pathologist.

For a case to be appropriate for personal assessment in an interpretive EQA system, it is necessary that, after the case has been circulated and the opinions of the participants collated:

i) one diagnosis or "category of response" has been agreed by a large proportion of the participants (normally over 75%, this is a matter for the scheme Organiser to agree with the Steering Committee). If not, then either the case is so difficult that it should be

[2] This superficially counterintuitive conclusion is easily justified. In a difficult cellular pathology case, failing to identify a single malignant cell might have a profound impact on the patient, but it may be an error that is entirely understandable (and is made by many of the scheme's participants). Conversely, misdiagnosis of a benign entity as another benign entity may have no effect on the patient whatsoever, yet (depending on the diagnoses in question) such an error might immediately call into question a pathologist's competence.

Note that, for the same reasons, the procedures defined by the College for the investigation of allegations of professional incompetence are quite distinct from the methods used to identify and correct patient harm.

in the "education and interest" category or there was something misleading about the material circulated; and

ii) there is no good evidence (such as might have arisen after circulation of the test material) that the most popular response was actually inappropriate; and

iii) any other responses proffered differ significantly from the most popular response.

Mechanisms for providing confidential quantitative feedback for individual participants should be defined in the scheme's SOPs. However, it should be made explicit in the scheme's documentation that the feedback is merely for guidance and does **not** have the rigour of a professional examination.[3]

The feedback mechanism must provide confidential personal reports to indicate each participant's performance, and to help the individual to reflect and draw comparisons with the relevant peer group.

5.4 Use of interpretive EQA reports: Taking appropriate action

Four areas can be identified where the output of an interpretive EQA scheme has specific consequences:

- spontaneous action by the individual participant
- discussion during annual appraisal
- action by the scheme organiser
- scrutiny during laboratory accreditation.

Spontaneous action by the individual participant
Any interpretive EQA participant who gets feedback indicating that even a single interpretive EQA response has been judged by their peers to be less than optimal should reflect on that result. A conscientious professional will consider carefully what remedial action will be justified, if any, to prevent a recurrence. This self-correction represents a major educational benefit of interpretive EQA schemes.

Discussion during annual appraisal
Each year, in addition to confirming participation in appropriate interpretive EQA schemes, the appraisal interview should include discussion of any cases where an interpretive EQA response has been judged to be less than optimal, in addition to whether any action points have been reached (see below). In most cases this will confirm that the doctor has already reflected on this result and has taken any necessary remedial action, but it is important to have independent confirmation. The appraiser may include specific items (such as CPD) in the doctor's personal development plan (PDP) for the next year. Interpretive EQA provides one component in the overall assessment of professional performance, together with input from all areas of the pathologist's scope of work during appraisal. If the appraiser is concerned that there may be an underlying risk to patient safety, it would be appropriate to escalate the problem to the doctor's responsible officer. This course of action is more likely to be appropriate if the doctor seems to lack insight or to be in denial that any problem exists.

[3] In 1998 the College working group commissioned a statistical analysis confirming that interpretive EQA schemes could not produce a numeric measurement of a pathologist's performance with anything approaching the rigour required of a professional examination; to do so would require pathologists to spend far longer reporting interpretive EQA cases than was practicable. Yet the benefits of providing quantitative feedback were undeniable, both for the individual participant and to provide the scheme organiser with an objective and transparent mechanism by which action to protect patients could be initiated, without the organiser having to make a subjective and therefore controversial decision about a colleague.

Action by the scheme organiser: defining 'action points'

The introduction of any objective assessment system inevitably means that some participants will do better than others. Experience of interpretive EQA scoring systems has shown that even pathologists who usually perform extremely well will occasionally make mistakes. Occasional and brief episodes of apparent sub-standard performance are therefore to be expected because, as explained above, interpretive EQA schemes do not have the statistical power to generate an assessment as reliable as a formal examination.

Even if it is persistent, sub-standard performance in interpretive EQA schemes does not **necessarily** equate with sub-standard performance in routine practice; rather it indicates there **may** be a problem, and the fact that the participant has not self-corrected demonstrates the need for peer review. If a definition of persistent sub-standard performance is properly drafted, occasions when it is detected should be infrequent.

The presence of an outlier with persistently sub-standard performance means that the organiser, as a doctor regulated by the GMC, is obliged to take appropriate action if the performance of a colleague is suspected of being a potential danger to patients.

Interpretive EQA schemes where the participants are individual practitioners therefore must define "action points" at which the organiser must take steps to investigate persistent sub-standard performance. Such action points must be clearly explained in the documentation of the scheme, and must be made known to participants. They must not require subjective interpretation by the organiser. They must be fair, and must not be activated unless a participant's interpretive EQA performance is clearly below the standards of the peer group of participants in the scheme.

It is impossible to identify a single minimum acceptable level of performance, as there will be variations between schemes in the difficulty of the cases and in the method of assessment. Even within one scheme, the difficulty of the cases and the methods of analysis are likely to vary considerably over time.

The best available approach is to compare individuals' results with those of their peers. The distribution of results in interpretive EQA schemes is invariably skewed, so non-parametric methods are the most appropriate tools for further analysis.

Nothing in this document detracts from the GMC requirement that any doctor should take appropriate action to protect patients if a colleague's performance appears to put patient care at risk. Consequently, if the organiser becomes convinced that action is needed, there is an obligation not to delay. However, if doubt remains in the organiser's mind as to whether rapid action is necessary, it will probably be prudent to put the data in anonymous form to the organising committee or participants' meeting and ask for advice on the most suitable course of action.

Definition of the first action point

After each circulation has been assessed, the organiser should put the participants into rank order of apparent performance. The participants in the lowest 3% ranking should be noted.[4] [5] [6] A low ranking on one occasion does **not** justify action.

---

[4] When this approach was first applied, in 1998, the action points were defined using the bottom 2.5% of ranked scores rather than the bottom 3%. Using that approach it was several years before any pathologist in the UK triggered the second action point. We therefore anticipate that a move to 3% will not result in an excessive number of referrals to the Chair of the Professional Performance Panel; but the Panel will monitor the consequence of this change (in consultation with the Steering Committee Chair) and may recommend adjustment.

[5] Consultation on this document resulted in a number of comments to the effect that pathologists will inappropriately be declared substandard performers as a result of random variation. This is mistaken. The following calculation is offered as reassurance, based on the (obviously incorrect) assumption that all participants are equally skilled and all variation is the result of chance.
In the first round, the probability of any participant falling into the bottom 3% is 0.03.
In the second round, the probability of those participants again falling into the bottom 3% by chance is 0.03 x 0.03 = 0.0009.
The probability of those two events happening in the first and third round is similarly 0.0009.

The first action point is defined as when a participant's code number has been noted in this way in **two out of three successive circulations** in which that individual participates.

Furthermore, although there is emphasis on the maintenance of confidentiality, these procedures do not preclude the development of local agreements to resolve problems. The participant in question may choose voluntarily to break confidentiality; for example, the participant may wish to inform appropriate managerial staff if it can be argued that sub-standard interpretive EQA performance is a consequence of poor local conditions of work.

Action by the scheme organiser at the first action point

The organiser sends a "first action point" letter to the participant, using a confidential mechanism in the interpretive EQA scheme office, so that the organiser remains unaware of the identity of the recipient of the letter. This indicates that the participant should discuss their interpretive EQA status during appraisal, and agree remedial steps as appropriate; for example, to include an item in the PDP if CPD is required. In addition, following a first action point letter, a failure to participate in any of the next three circulations will be regarded as a result in the bottom 3% for that circulation.

Alternatively, the participant may decide to withdraw from the area of service covered by the EQA scheme, and adjust their scope of work accordingly. The participant would then have to state this to the scheme organiser, formally withdraw from the scheme and inform local management.

The recipient of such a letter will be asked to write to the organiser via the EQA secretary and thus be identified only by code number, confirming that the letter has been received and confirming that this will be discussed during appraisal and specifically addressed in the PDP; or that the participant has ceased to deliver a service in the area covered by the interpretive EQA scheme. If such an acknowledgement is not received within a month, the organiser will write again. If an acknowledgement is not received within two months of sending the original letter, the organiser will contact the Chair of the Professional Performance Panel, as outlined below.

Definition of the second action point

After the first action point has been reached, the organiser should record the event and outcome against that participant's code number.

If the participant is continuing in practice in the area covered by the scheme, the second action point is triggered if the participant is in the lowest 3% of the participant ranking in any two of the next three successive circulations. However, at this stage, any failure to participate in the next three circulations will be recorded as equivalent to a score within the bottom 3% of the ranked order. Otherwise a failure to participate could cause a delay in further assessment. If failure to participate is due to a genuine and unavoidable reason such as ill health, the organiser is in no position to verify such a claim so the process should not be amended.

This closer surveillance should be continued for three circulations, after which the conditions of participation should return to those applied to all other pathologists in the scheme.

The presence or absence of a plausible reason for the sub-standard performance should not affect this period of closer surveillance.

Action by the scheme organiser at the second action point

When the second action point is reached, the organiser will inform the Chair of the Professional Performance Panel, who will initiate an investigation. The organiser will provide

---

The probability of those two events happening in the second and third round is similarly 0.0009.
Hence if all participants perform equally apart from random variation, the probability of any one participant triggering the first action point in the first 3 rounds is 0.0009 + 0.0009 + 0.0009 = 0.0027.
The probability the same thing happening in subsequent sets of three circulations is the same, so:
The probability of the second action point being triggered by chance in two consecutive sets of three circulations is 0.0027 x 0.0027 = 0.00000729. It seems far more likely that variation in performance will account for such an event.

6 Scheme organisers who prefer to use the 3rd centile rather than 3% should be free to do so.

to the Panel Chair and to the participant details of the interpretive EQA responses that have resulted in this referral.

The task of the investigation is to determine whether the low interpretive EQA scores relate to standards of routine practice that may put patient care at risk. The investigation will therefore seek all possible explanations of the low scores, potentially including a review of the nature of the interpretive EQA scheme but concentrating on the participant's routine practice, including conditions of work. The emphasis will be on tracing problems and implementing remedial measures.

The Panel Chair may choose to delegate this phase of investigation to another respected pathologist. This is likely to be essential if the Chair and the participant work in very different specialties of pathology.

The Chair (or delegated investigator) may discuss the problem with the other members of the Panel, but in such a way that will not reveal to the other members the identity of the pathologist under review.

The Professional Performance Panel has no power to compel a pathologist to comply with this process.[7] However, if a pathologist refuses to cooperate, the matter should be referred without further delay to the participant's responsible officer (or an appropriate professional regulator or manager).

These steps should be completed with reasonable speed; a few weeks at most. If the Chair of the Professional Performance Panel has still not been satisfied of an innocuous explanation, or if any lack of cooperation appears to be slowing the evaluation, the Chair will inform the doctor's responsible officer.

These procedures should be activated only in exceptional circumstances, and should cause no more concern to interpretive EQA participants than the current possibility of an allegation of incompetence arising from other sources. The main purpose of interpretive EQA schemes should remain educational. We anticipate that interpretive EQA schemes will continue to be valued by pathologists for this reason.

6 Scrutiny during laboratory accreditation

When interpretive EQA schemes were first established there was agreement, including agreement by the Department of Health, that their principal function is educational; that scores or rankings in EQA schemes do not represent a rigorous assessment of a pathologist's competence, but demand interpretation in context; and as a result, personal feedback from EQA schemes should remain confidential (see Appendix).

Since then, the establishment of confidential medical appraisal has led the College to agree that interpretive EQA scheme results should be shared during annual one-to-one confidential appraisal meetings, to maximise their educational value. But the College does not agree that interpretive EQA scheme results should be made available to third parties such as hospital managers or accreditation assessors.

If a laboratory states that it includes monitoring of interpretive EQA results as one of the mechanisms to ensure the ongoing competence of its pathologists, then accreditation assessors working to ISO15189 may ask to see evidence of that mechanism being used.

However, a laboratory would be unwise to make such a statement, because interpretive EQA does not have the rigour of a professional examination, and because laboratory managers will not themselves have access to detailed interpretive EQA reports of pathologists in their department.

Consequently, in respect of interpretive EQA schemes, it is the opinion of the College that laboratory accreditation assessors should at most be entitled to:

[7] It is noted that not all pathologists in the UK are members of the College.

- confirmation that all senior members of staff (those undertaking independent generation of interpretive reports) are participating in all relevant interpretive EQA schemes, where such schemes exist and have been confirmed by the College Steering Committee to be conforming to this guidance. (A list of interpretive EQA schemes that have College approval and submit annual data to the College will be available on the College website.)
- confirmation that all senior medical members of staff are undertaking annual appraisals in line with GMC and College guidance, at which the results of interpretive EQA participation are discussed.

Individual laboratories will need to agree with accreditation assessors how such confirmation might be delivered. This might include written assurances from heads of departments and Responsible Officers that interpretive EQA outputs are discussed during annual appraisal meetings, in addition to the existence of the mechanism set out in this document whereby scheme organisers act in the event of persistent sub-standard performance.

Accreditation assessors, like laboratory managers, should **not** ask to see details of individual interpretive EQA performance reports. Such reports require careful interpretation. Appropriate methods for such interpretation, as described above, will be in place if there is appropriate participation in approved schemes in a laboratory where medical staff comply with GMC revalidation requirements. Accreditation assessors, like laboratory managers, are **not** entitled to ask to see full medical appraisal records, because such records are confidential and may contain confidential material irrelevant to a laboratory assessment.

It is recognised that non-medical clinical scientists may have similar responsibilities to medical pathologists and may be involved in interpretive EQA schemes, but they are not subject to revalidation. They should, however, participate in annual NHS appraisals. An open discussion of interpretive EQA results should therefore be a mandatory part of such appraisals.

7 Action to be taken by interpretive EQA scheme organisers who wish to obtain RCPath approval for their schemes

- prepare SOPs describing how the principles above are met. A template approved by the RCPath Interpretive EQA Steering Committee will be made available to provide assistance.
- submit SOPs to the Steering Committee for approval, with any fee prescribed by RCPath Council to cover the cost of such scrutiny
- provide the College with the name of the scheme and its organiser and secretary. These will be displayed on the College website, together with a link to the scheme's website for further information.
- send annual reports to the Steering Committee documenting the number of rounds, cases, accepted cases, number of participants and action points during the year, annual subscription, accreditation status, and a brief outline of any innovations
- pay the College annual levy for its governance support for interpretive EQA schemes.

Appendix Background and purpose of interpretive EQA

External quality assessment schemes in laboratory medicine were first introduced and developed in the UK in the 1950s and 1960s, exclusively in relation to quantitative laboratory assays. A number of core operating principles were established in that period, including:

- some form of 'test' material is procured or prepared by a central 'organising laboratory' under the supervision of a 'scheme organiser'. This test material is delivered to participating laboratories such that they all receive equivalent material for examination.
- the test material should be representative of the laboratory's routine diagnostic workload
- the laboratory should, as far as possible, analyse the test material in the same way that it would analyse a routine specimen
- the result(s) should be returned to the organising laboratory
- the organising laboratory should identify a 'target value' for each analyte in each sample. This might be achieved by the use of a highly accurate reference assay that is not applicable to routine practice, or by using the consensus of the participating laboratories, depending on the analyte (the method of identifying the target value has been controversial in quantitative EQA schemes, but the arguments involved are not relevant to this document).
- the organising laboratory should compare each laboratory's submitted results with the target values and generate a confidential report for each participating laboratory
- it should initially be the responsibility of the participating laboratory to investigate any discrepant results. In addition, a mechanism should exist whereby the scheme organiser should offer assistance to any laboratory that persistently generates unusually discrepant results. In cases where corrective action is not successfully taken, a mechanism should exist to ensure that patient safety is not compromised.

In the late 1980s and early 1990s, several individuals started to extend these principles beyond quantitative laboratory output to laboratory reports involving professional interpretation and judgement, notably in cellular pathology. Some schemes evolved from existing 'slide clubs', which had a purely educational function. The development of interpretive EQA schemes along these principles was hastened by a number of reports that gained a high profile in the public press at the time. In one notable case, members of an informal slide club had been well aware that a pathologist was frequently contributing incorrect diagnoses, but no one felt it was their responsibility to report the problem. Several patients suffered severe consequences as a result of what proved to be a health-related performance problem. It was at this time that the GMC introduced the duty of all doctors to take steps to protect patient safety if they had reason to believe that a colleague's work might put patients at risk. It became obvious that slide clubs or EQA schemes would need a mechanism to determine when a pathologist's performance justified reporting to an appropriate authority, otherwise scheme organisers could be subjected to severe criticism or even disciplinary action.

To address this problem, and other issues raised by the translation of quantitative EQA to interpretive EQA, the College established a working group that published a report in 1998 entitled *Recommendations for the development of histopathology/cytopathology EQA schemes*. The guidance in that document has not been updated or explicitly extended to other pathology disciplines until now.

Although interpretive EQA in the UK started on the basis of examination of microscope slides, schemes with many of the characteristics of interpretive EQA schemes were established to address interpretive aspects of practice in other laboratory disciplines. It was recognised that a variety of materials might be used. For example, it is perfectly possible to circulate macroscopic images, numeric laboratory results or descriptions of management problems, as long as it is clear that the response required is a professional judgement and the principles set out in this guidance document are adhered to. Some interpretive schemes have laboratories, rather than individual practitioners, as their participants; this document is not directed at them.

The history of evaluating the quality of responses

In 1998 the concept of allocating 'scores' to the interpretive opinions of pathologists caused much controversy. **The College working group commissioned a statistical analysis which confirmed that interpretive EQA schemes could not produce a numeric measurement of a pathologist's performance with anything approaching the rigour required of a professional examination;** to do so would require pathologists to spend far longer reporting interpretive EQA cases than was practicable. Yet the benefits of providing quantitative feedback were undeniable, both for the individual participant and to provide the scheme organiser with an objective and transparent mechanism by which action to protect patients could be initiated, without the organiser having to make a subjective and therefore controversial decision about a colleague. The initial controversy was resolved partly by insisting on high levels of confidentiality in relation to personal interpretive EQA reports, but also by an explicit statement from the Department of Health, in the form of an 'Executive Letter' to all NHS chief executives (EL(98)2).[8] This Department of Health Executive Letter included the statements:

…their principal function is educational rather than as a means of performance assessment. There are other systems in place for the early identification of potential problems which might affect patient care, and the identification of individual poor performance through an EQA scheme will be exceptional.

…the level of performance will in most situations remain confidential to the participant. However, mechanisms are being developed for informing Trust Medical Directors and/or other appropriate authorities of individual poor performance where this is necessary to protect patient safety and/or comply with General Medical Council guidance or new arrangements for clinical governance within Trusts.

At that time, the "*mechanism*…" "*…for informing Trust Medical Directors and/or other appropriate authorities of individual poor performance*" was the process for identifying, reporting and offering remediation for persistent sub-standard performance set out in the College's 1998 publication.

Since then, we have seen the introduction of medical appraisal and revalidation, with the appointment of Responsible Officers. The annual appraisal interview represents an excellent forum for the confidential discussion of interpretive EQA results. **The College has recommended that the annual appraisal of pathologists who participate in appropriate interpretive EQA schemes now includes a review of the results of each interpretive EQA, beyond the previous requirement for confirmation of participation.** In almost all cases, this should feed only into the formative aspects of the appraisal; it is likely to inform the following year's PDP. The main role of interpretive EQA schemes therefore remains educational and preventative through early recognition and remedial action by the individual. However, the obligation on the appraiser for triangulation of interpretive EQA outcomes with other quality indicators of professional performance, and to report matters that might adversely affect patient safety to the responsible officer, represents an additional route by which sub-standard performance of pathologists might be identified and investigated.

[8] Department of Health. *Oversight of provision of external quality assessment schemes in histopathology, cytopathology, cytogenetics and molecular genetics for pathology laboratories* - EL (98)2, 1998. http://webarchive.nationalarchives.gov.uk/20130107105354/http://www.dh.gov.uk/en/Publicationsandstatistics/Lettersandcirculars/Executiveletters/DH_4017775

History of the governance of interpretive EQA schemes

In 1998, two separate committees provided oversight of interpretive EQA schemes:

1. A Steering Committee, composed largely of scheme organisers, was responsible for providing guidance on how interpretive EQA schemes should run, and for confirming that schemes complied with College guidance. The Steering Committee also provided a route through which complaints by scheme participants about how schemes were being run could be considered.

2. An Advisory Panel (formally the Advisory Panel of the Joint Working Group on Quality Assurance) was responsible for agreeing definitions of persistent sub-standard performance, and for taking action when a scheme organiser reported persistent sub-standard performance.

Referrals for persistent sub-standard performance proved to be very infrequent. These two committees were therefore merged. The resultant Advisory Panel attempted to combine both functions, but only in respect of cellular pathology. It also attempted to cover technical EQA schemes in cellular pathology, which have a quite different function. Perhaps unsurprisingly, some scheme organisers complained that this was not working well.

A system for the accreditation of EQA schemes was developed by Clinical Pathology Accreditation Ltd (subsequently acquired by UKAS). However, this was a complex system, designed principally with large quantitative EQA schemes in mind. The model was widely perceived as being inappropriate and disproportionate for small interpretive EQA schemes. Accreditation by CPA/UKAS has not been maintained by the majority of such schemes.

By updating the principles and guidance for interpretive EQA Schemes in laboratory medicine, the College has taken the role of providing a validation route for interpretive EQA Schemes which is proportionate and ensures schemes follow a standardised structure and operating system.