

IRISH EQA SCHEME IN GENERAL HISTOPATHOLOGY

SOP 1.

General Description of Scheme

1. The Irish EQA Scheme in General Histopathology is sponsored and supported by the Faculty of Pathology, which represents the host organization for the Scheme
2. The Histopathology Working Group of the Faculty of Pathology provides the governance for managing Persistent Substandard Performance in the Scheme when the Second Action Point has been reached (see below 5), as well as providing a resource for Scheme members if the First Action Point has been reached.
3. IEQAS (Irish External Quality Assessment Scheme) is the Scheme Administrator. IEQAS is a not-for-profit organization established in 1981 that provides and manages technical EQA schemes, both directly and in collaboration with other European providers of EQA schemes. Since 2012, it has taken on the role of Scheme Administrator for the Irish EQA Scheme in General Histopathology, which is a diagnostic rather than technical scheme.
4. The members of the Scheme provide cases for circulation and collectively, via their participation at the Members' Meeting, judge and score responses in each circulation, based on the model of peer review. By joining the Scheme, members agree to the Standard Operating Procedures, including stating any diagnostic areas within the scope of the Scheme which is outside their reporting repertoire, committing to providing cases when requested and committing to consistent participation. IEQAS or its Steering Committee play no part in providing or choosing cases for circulation, in judging and scoring responses to circulations or in providing mechanisms for handling Persistent Substandard Performance.
5. The Scheme members agree a Steering Committee, from whom is chosen a Scheme Organiser, who acts as the key liaison with IEQAS, the Faculty of Pathology and the Histopathology Working Group of the Faculty of Pathology.
6. The aims of the Scheme are:
 - To contribute to continuing medical education for histopathologists who continue to have a fully or partly generalist diagnostic practice.
 - To assist in promoting and maintaining professional standards in general diagnostic histopathology reporting.
 - To provide individual performance appraisal to general histopathologists based on the principle of peer review.

- To promote dialogue and discussion between general histopathologists.
 - The significant limitations of any such diagnostic EQA scheme to reflect or assess real life diagnostic practice are acknowledged.
7. The Scheme comprises two circulations of 12 scoring slides each per year, with scope for including additional non-scoring cases of a purely educational nature. Members must have a minimum participation of two out of every three circulations, except in specific circumstances (see 8 below). The cases are provided by members when requested, who judge them appropriate for submission to a Diagnostic EQA Scheme in General Histopathology. The suitability of cases included and the scoring of responses to cases are agreed by members present at the bi-annual Members Meeting.
 8. Individual members each receive personal feedback, with the agreed scoring for their responses to the cases in a circulation compared to the scoring for the membership overall. Persistent Substandard Performance in the Scheme is defined by a First Action Point reached when a member has a score in the lowest 2.5% in two out of three successive circulations and a Second Action Point reached when the member has a score in the lowest 2.5% in two out of the three next circulations (which they are under obligation to participate in, having reached the First Action Point).
 9. Members have a confidential PIN that is used to identify their responses and in communication of any other confidential matters. Only the non-medical Scheme Administrator is aware of the link between members' names and their PINs. This strict confidentiality is maintained in all except defined exceptional circumstances.
 10. The Scheme is run on a not-for-profit basis. A fee is levied on Scheme members, the fee being payment for the services provided by the Scheme Administrator, IEQAS. The Scheme Organizer and the members of the Scheme Steering Committee provide their services without charge
 11. The Scheme's dedicated email is histo@ieqas.ie
 12. The current Scheme Organiser is:

John O'Dowd
Bon Secours Hospital
Dublin 9
odowdj@iol.ie
087 232503

13. The contacts for the Scheme Administrator , IEQAS are:

Patricia Howley (Operational Manager) and Hazel Graham
(Quality Manager),
IEQAS (Irish External Quality Assessment Scheme),
B06 Nutgrove Enterprise Park,
Rathfarnham,
Dublin 14
histo@ieqas.ie
01 4957356
www.ieqas.ie

14. The current Steering Committee are:

Margaret Sheehan, University College Hospital, Galway
Gerry O'Dowd, Letterkenny General Hospital
Michael Jeffers, AMINCH
Elaine Kay, Beaumont Hospital

History of the Scheme

The Scheme was started in 2007, modeled on the well established Scotland and Northern Ireland EQA Scheme in General Histopathology and following two pilot circulations in 2005 and 2006. Although the Scheme was initially run on an ad hoc basis, its procedures closely followed those of the Scotland and Northern Ireland Scheme. The latter, in common with all UK-based general and specialist diagnostic histopathology EQA schemes, followed the document "Recommendations for the Establishment of Histopathology/Cytopathology EQA Schemes" published by the Royal College of Pathologists in 1998 in drawing up their SOPs, the Royal College of Pathologists' NQAAP in Histopathology being the body providing governance for Persistent Substandard Performance. The educational purpose of all such schemes, based on the principle of peer review, was emphasized, as were their limitations as a tool in either reflecting or assessing the real life workload and activity of diagnostic histopathologists.

The scoring system for the Scheme was changed in 2011, starting with Circulation 7. The revised scoring system is similar to the one used by the UK National Specialist Dermatopathology EQA Scheme and allows members to offer a differential diagnosis for cases if they feel it is appropriate, with a requirement to weight the differential diagnoses offered. This new scoring system replaced that borrowed from the Scotland and Northern Ireland Scheme, which was felt to unfairly penalize participants who followed the guidelines in offering a single working diagnosis (albeit that was ultimately judged incorrect), whilst giving an advantage to those participants who offered a broad differential diagnosis despite not adhering to the guidelines to offer a single working diagnosis.

The Board of the Faculty of Pathology agreed to provide governance for the Scheme, particularly with regard to the issue of the possibility of Persistent Substandard Performance being identified, during 2011. It was felt most appropriate by the Board to do so via the Histopathology Working Group of the Faculty of Pathology. This led to a formal set of Standard Operating Procedures being adopted at the Members Meeting in October 2011, with Circulation 8 being the first circulation to operate under the terms of these SOPs

The Faculty of Pathology, as sponsor of the Scheme, had allowed the non-medical Administrator of the Faculty to provide some administrative support for the Scheme and the Scheme Organizer, Steering Committee and members are grateful to successive Faculty Administrators for their hard work in supporting the Scheme and allowing it to evolve and continue. However, it became apparent that the medium term viability of the Scheme required a different approach to administration of the Scheme and following discussion at the Members Meeting in September 2012, it was decided that IEQAS was a suitable partner to provide the role of Scheme Administrator. Circulation 9 was the first under the aegis of IEQAS as Scheme Administrator.

Although the Scheme had historically been free of charge, the choice of IEQAS involves the necessary levy of a small fee for participation, to commence with Circulation 10 (Circulation 9 having been funded by residual monies awarded by the Medical Council to the EQA Scheme as a quality assurance/audit project).

List of SOPs

1. General description of scheme, History of Scheme and List of SOPs
2. Scheme membership & Participation
3. Enrolment of new members and Payment of Participation Fee
4. Scope of scheme
5. Exclusion of sub-specialty areas from repertoire by members
6. Obtaining case material & Failure to provide cases
7. Initiating a circulation
8. Submission and analysis of responses
9. Members meeting and Review session
10. Scoring of responses
11. Feedback to members
12. Confidentiality
13. Persistent substandard performance
14. Roles and responsibility of the Scheme Organiser and Scheme Administrator
15. Communications and complaints. Retention of material and records

Addenda

- A. Membership Application Form
- B. Payment request
- C. Current list of hospitals circulated and contact pathologists in each
- D. Letter sent to member if the First Action Point related to Persistent Substandard Performance has been reached
- E. Letter sent to member by Chairman of HWG if the Second Action Point related to Persistent Substandard Performance has been reached.
- F. History or revisions to SOPs

IRISH EQA SCHEME IN GENERAL HISTOPATHOLOGY

SOP 2.

Scheme Membership & Participation

Scheme Membership

The Scheme is aimed at those histopathologists in Ireland who report general histopathology independently and on an ongoing basis. Histopathologists filling short term locum positions are not eligible for membership, although locum histopathologists who have an intention to practice in Ireland on an ongoing basis, such that they can ensure consistency of participation, may participate. Likewise, histopathologists who have retired from their principal post but intend to continue to practice, even in ad hoc way, may participate, so long as they can ensure consistency of participation and maintain access to circulated material. Members from Northern Ireland are welcome.

The Scheme is not suitable for those histopathologists with an exclusively specialist practice. Specialist Registrars and other trainees and short term locums may not become Scheme members but are encouraged to look at the slide circulations. Non members may attend the Members Meeting and may participate in the discussion, although they must identify themselves as non members, but they may not vote with regard to the scoring of responses, acceptance of or modification to SOPs etc.

Participation

The minimum acceptable level of participation in the Scheme is two out of three consecutive circulations (rounds), calculated on a rolling basis, provided the First Action Point relating to the possibility of Persisting Substandard Performance (PSP) has not been reached (see SOP 13).

When a Scheme member is away from work for a protracted period (e.g. due to illness, sabbatical leave or maternity/paternity leave), the Scheme Administrator should be notified so that their membership of the Scheme is suspended and then re-notified on their return to work to reactivate Scheme membership.

Failure to maintain the minimum level of participation (that is, members who fail to submit responses to two consecutive circulations) leads to a Letter of Enquiry being sent to the member seeking reasons and failure to respond to this will terminate Scheme membership.

Failure to respond to three successive circulations automatically terminates scheme membership.

Non-participation in any of the three circulations following triggering of the First Action Point counts as a substandard performance in the relevant circulation (see SOP 13).

IRISH EQA SCHEME IN GENERAL HISTOPATHOLOGY

SOP 3.

Enrolment of New Members

Any histopathologist wishing to join the Scheme should contact the Scheme Administrator at histo@ieqas.ie. All prospective members are directed to an online copy of the Scheme's SOPs and asked to read them. The prospective member then downloads a Scheme Membership Application Form (see Attachment 1) and completes it, signs it and returns it by post to the Scheme Administrator. The Scheme Membership Application Form and the Scheme's SOPs are available on the IEQAS website www.ieqas.ie. The member completes and signs the Membership Application Form

- To indicate that they have read the SOPs and wish to participate in the Scheme on the terms outlined in those SOPs or on any subsequent version of same that may become current
- To indicate any sub-specialty areas that they wish to be excluded from their reporting repertoire (see SOP 5)
- To give their name, contact details and the email address (or addresses) which they wish to use for correspondence with the Scheme

On receiving a completed Scheme Membership Form, the Scheme Administrator assigns the new member a confidential PIN (the PIN is sent to the new member by post) and enters the new member's details (including PIN) on the confidential database maintained by the Scheme Administrator (see SOP 12).

Payment of Participation Fee

IEQAS are a not-for-profit organization but will levy a participation fee on Scheme members for their role as Scheme Administrator, for one half year for Circulation 10 and for a full year for each of two circulations afterwards. Members must pay their participation fee before they are considered to have participated in a relevant circulation or circulations. Please see Addendum B.

IRISH EQA SCHEME IN GENERAL HISTOPATHOLOGY

SOP 4.

Scope of Scheme

The cases selected for the Scheme are intended to reflect a routine general histopathology practice and should not include bizarre or controversial cases. The Scheme may include cases from the following categories or systems:

- Skin
- Subcutaneous and soft tissue
- Gastro-intestinal
- Gynaecology
- Urology
- Head & neck/ENT
- Endocrine
- Respiratory/thoracic
- General surgical pathology (reflecting the potential diagnostic material that could be submitted to a histopathologist in a general hospital and to include recognition of pathological entities that are not necessarily site-specific)

Areas of restricted or exclusively specialist practice (such as paediatric pathology, medical renal pathology, breast pathology and neuropathology) or cases usually considered to require a referral opinion are excluded. Cases requiring a complex and/or multi-disciplinary work-up for diagnosis (such as many lymphomas) are excluded. Autopsy and cytology cases are excluded.

The type of case selected is inherently limited by the need to generate sufficient representative slide material for circulation. In addition, the cases selected are intended to be suitable for diagnosis on the basis of the submitted slide material (most usually a single H&E) in conjunction with provided clinical details, macroscopic description and (if any) stated results of special and/or immunohistochemical stains or other studies. Both of these factors limit the ability of the Scheme to include the range of cases that would reflect the real life workload of a general histopathologist.

IRISH EQA SCHEME IN GENERAL HISTOPATHOLOGY

SOP 5.

Exclusion of Sub-Specialty Areas from Repertoire by Members

If a member does not routinely report certain specific categories of case material, they may opt to notify the Scheme Administrator that they wish such categories to be excluded from their reporting repertoire. The case categories are outlined under Scope of Scheme (see SOP 4). Thus, if a case from such a category is included in a circulation, the respondent indicates that it is “outside repertoire” on the answer sheet and it is scored as if a correct answer was given. However, this cannot be done retrospectively. Prospective notice that the case category was “outside repertoire” must have been given for such responses to be considered valid. Otherwise, the response is considered equivalent to not providing a response at all and is scored as 0.

The Certificate of Participation that is issued to each valid Scheme member will include a statement of those case categories that the member has opted to exclude from their reporting repertoire.

If a member opts to exclude more than a few case categories from their reporting repertoire, reflecting a significantly sub-specialised practice, consideration should be given by the member as to whether participation in schemes of a more specialist nature is appropriate.

IRISH EQA SCHEME IN GENERAL HISTOPATHOLOGY

SOP 6.

Obtaining Case Material & Failure to Provide Cases

Obtaining Case Material

Each Scheme circulation comprises twelve scoring cases, with the possibility of additional material of an educational nature to be included which isn't scored. Cases for circulation in the Scheme are submitted in rotation by the membership. Members are asked in rotation to supply two cases each. Ten members are asked on the occasion of each circulation. The selection of members to provide cases is at random, but will exclude those who have previously submitted cases until the entire membership has been sent requests for cases. At the Scheme Organiser's discretion, members may be asked to supply cases from a specific system or systems or to avoid supplying cases of a specific type in order to try and achieve a balance of cases from different systems across circulations.

Use of archival material for EQA purposes should not require the approval of either local ethical committees or the individual patient's consent, so long as:

- No more tissue has been removed from the patient than that required for their ordinary medical care
- Use of the material for EQA does not compromise routine diagnostic assessment
- The material supplied for EQA is anonymous
- The Scheme or the Scheme Administration is a not-for-profit activity

Members are asked to select cases for inclusion so that:

- Cases reflect a routine general histopathology workload
- A single definite diagnosis should be possible on the basis of the H&E section provided, in conjunction with the accompanying details
- Bizarre or controversial cases are avoided
- Entirely banal cases are avoided
- Cases in which only a differential diagnosis can be offered are not suitable in general
- Each case should have only one primary pathological process present

Members send twenty H&E stained slides for each case to the Scheme Organiser, including all relevant details available to them at the time of diagnosis (including clinical details, macroscopic description and the results of any special stains, immunohistochemical stains or other studies performed) but without a diagnosis, so that the Scheme Organiser can ensure their own valid participation in the Scheme.

The submitting pathologist should ensure that each of the twenty H&E slides submitted for each case is representative and permits diagnosis. The twenty H&E slides submitted should be without any identifying labels or numbers.

Members should keep their own record of the cases that they submit, so that if there is a conclusive disagreement with their prior reported clinical diagnosis following completion of a slide circulation, appropriate action can be initiated if clinically indicated. This is the responsibility of individual members.

The Scheme Organiser keeps a record of the submitting pathologist and the specimen details for each case received. The Scheme Organiser maintains an archive of the cases submitted.

Failure to Provide Cases

If a member fails to provide cases for a circulation when requested, they are asked to provide two cases for the next circulation. If the member again fails to provide cases, they are asked a third time to provide cases for the following circulation. If they fail to comply, they cease to be Scheme members and cannot become valid members again for a period of three years.

IRISH EQA SCHEME IN GENERAL HISTOPATHOLOGY

SOP 7.

Initiating a Circulation

The Scheme Organiser, a Steering Committee member or some combination of same selects a set of twelve cases from the archive of cases submitted as suitable for circulation as part of the EQA scheme. If this is done by more than a single person, the people involved do not communicate their preferred diagnoses regarding each case to each other, the aim of the exercise being only to assemble a set of twelve cases that are judged appropriate and aim to achieve balance between different systems within and across circulations. Although they have previewed the cases, they subsequently participate in the circulation in the same manner as other Scheme members.

The Scheme Organiser transfers the slides for the selected twelve cases, marking each set of slides as “1”, “2” etc, with pencil, to the Scheme Administrator, who then formally labels and boxes the slides. In general, one box of slides is sent to each larger laboratory, whilst smaller laboratories are organised into pairs, with a requirement that the slide box is sent from the first laboratory in the pair to the second by a specified date halfway through the circulation, so that each of these smaller laboratories has the slide box for six weeks. A nominated pathologist is identified in each of the laboratories to which the slide box is addressed (as well as a nominated pathologist in the second laboratory in a pair). However, it is the responsibility of individual Scheme members in each laboratory to access the slide boxes. See Attachment C, which provides a current listing of laboratories and contact pathologists to which the boxes are sent.

Slide boxes are sent only to laboratories in which there are Scheme members. Scheme members who maintain a practice at several sites are requested to access the slides at the designated laboratories, so that logistical difficulties in circulating slides to multiple sites, with multiple handovers, are minimised. If retired histopathologists wish to continue participating as Scheme members, they must make arrangements to access the slide boxes at the designated laboratories. Slide boxes will not be sent to private addresses.

In the case of the smaller paired laboratories, it is the responsibility of the nominated pathologist in the first laboratory to send the slide box on to the nominated pathologist in the second laboratory by a specified date halfway through the circulation. The Scheme Administrator will send an email reminder on the specified date to each of the nominated pathologists in the first laboratory and the second laboratory in each pair.

Each circulation lasts three months, with a final date for submission of responses specified. At the start of each circulation, the Scheme Administrator writes to members informing them of the time scale and relevant dates for each circulation and (if available) the date, time and venue of the

Members' Meeting. Each letter is accompanied by a pro-forma Answer Sheet that includes a list of the cases in the circulation with all their relevant clinical and other details. The Answer Sheet is drawn up the Scheme Organiser. A copy is available on the Scheme Administrator web site.

Members are sent by email a reminder to submit their responses two weeks before the final date for submission of responses. This also contains a reminder of the date, time and venue of the Members' Meeting and a listing of the PINs of those members who have already submitted responses to the circulation. Members may keep the slide box at the end of the circulation for review purposes if required. All communication with members concerning initiation and progression of a circulation as described above is via email.

IRISH EQA SCHEME IN GENERAL HISTOPATHOLOGY

SOP 8.

Submission & Analysis of Responses

Members should offer a single working diagnosis as their response to each case. Members have been asked to submit cases for inclusion in the EQA Scheme on the criterion that a single definite diagnosis should be possible on the basis of the H&E section provided, in conjunction with the accompanying details provided on the Answer Sheet.

Discussion of cases with colleagues or offering consensus diagnoses between colleagues is not permitted but access to textbooks etc is appropriate. Obviously, this cannot be supervised and as in all such schemes, relies on maintaining good faith amongst the participants members. This is a further reason why any scheme of this kind is primarily educational and is not a suitable tool for performance assessment in real life practice.

Failure to answer a case is considered equivalent to an incorrect response and scores 0. If a case falls within a category that a member has indicated prospectively is outside their reporting repertoire, they should indicate that it is "outside repertoire" as their response (see SOP 5) and the case is scored 1, as if a correct answer has been given. If no such prospective notice has been given but the answer given is "outside repertoire", the case scores 0.

If a member cannot offer a single diagnosis for a case and feels instead that a differential diagnosis is appropriate, a differential diagnosis may be entered under the headings on the Answer Sheet, but the member must give a relative weighting for each of the differential diagnoses offered such that overall the weightings add up to 10. No more than three differential diagnoses should be offered.

Any other comments that the member thinks appropriate with respect to a case regarding additional information they may wish to offer, additional studies they think appropriate, the quality of the material or the appropriateness of the case should be entered under the "Comments" heading for each case on the Answer Sheet. However, comments are recorded only and not scored. Only the responses indicated under "Diagnosis" are scored.

Members return completed Answer Sheets to the Scheme Administrator by email. Members should save the pro forma Answer Sheet as a Word document on to their desktop, complete it and save the completed document, sending a copy by email to the Scheme Administrator. Return by email is preferred as it enhances confidentiality and traceability, avoiding the possibility of identifying handwriting. Each page of each Answer Sheet should be marked with the member's PIN and the date of completion. Nowhere should a member mark their name. Members should keep their own copy of their completed Answer Sheet.

When the Scheme Administrator receives a completed Answer Sheet by email, it is printed off and checked for completeness (including member's PIN on each page) and any problems addressed at that stage by direct correspondence between the Scheme Administrator and/or Scheme Organizer via the Scheme Administrator and the member. Once satisfied that the response is complete, the Scheme Administrator records that the member's response has been received on the database, sends an email acknowledgement to the member and removes all marks potentially revealing the identity of the member (e.g. envelopes or email addresses). The Scheme Organizer or member(s) of the Steering Committee who selected the cases participate in and respond to each circulation in the same way as other members. Following the final date for submission of responses to a circulation, the Scheme Administrator gives the Scheme Organizer the collected Answer Sheets. The Scheme Organizer collates the responses to produce a summary listing for each of the cases in a circulation of the offered diagnoses and their relative popularity (taking account of weightings for those responses including a differential diagnosis).

This summary listing is sent to members of the Steering Committee. An email containing the summary listing of the responses and their relative popularity, a list of members sending responses and a notification of the date, time and venue of the Members Meeting is sent out to all members.

IRISH EQA SCHEME IN GENERAL HISTOPATHOLOGY

SOP 9.

Members Meeting & Review Session

There is a Members' Meeting held twice a year to discuss the cases and the members' responses to the cases in each circulation. This may be timed to coincide with the Annual Meeting of the Irish Society of Surgical Pathology and/or the Faculty of Pathology Annual General Meeting and should last for an hour. All members are invited to attend the meeting and at least 10% of respondents should be present for it to be considered quorate. An Attendance Sheet is circulated at the Members Meeting. A member can email the Scheme Organizer if they cannot attend the Meeting but wish to comment on some aspect of the Scheme or a case that they wish discussed at the Meeting. The Members Meeting is an open meeting but only Scheme members can vote. Non-members should identify themselves as such before they contribute to a discussion. The meeting is chaired by the Scheme Organizer or a member of the Steering Committee and the conduct of the meeting briefly summarized.

The Members' Meeting allows members to discuss:

- The general management and organisation of the Scheme. Any suggestions to change, extend or improve the Scheme or its SOPs are welcome.
- The cases from the previous circulation and how best they should be used for individual performance appraisal based on the principles of peer review and individual feedback, In particular:
- If a case is suitable for individual performance appraisal as part of an EQA Scheme in General Histopathology. Unsuitable cases include those where less than 80% of responses indicated a correct diagnosis or where the material was deemed inadequate to reach a specific diagnosis.
- How the responses to suitable cases should be scored.
- The latter two items are done on a case by case basis.

The Scheme Organizers or members of the Steering Committee or any combination of same present the cases and their responses. In addition, participation or presentation from those pathologists who originally submitted the cases is welcomed. The "correct" diagnosis for a case is defined as one in which there is at least 80% agreement among the members responding to that circulation on the diagnosis, assuming that there is no good evidence that the majority diagnosis provided by the members is wrong.

Changes to or adoption of new SOPs and judgments regarding whether a case is suitable for scoring and how responses should be scored are ideally made by consensus of the members present. If there is disagreement, decisions are made by majority (>50%) agreement, using a show of hands if necessary.

If the Members Meeting is not quorate, members are subsequently circularized by email with a proposed scoring generated by the Scheme Organizer and members of the Steering Committee. Any objections to the proposed scoring should be made by email within two weeks and if these are substantive, an email ballot is organized.

IRISH EQA SCHEME IN GENERAL HISTOPATHOLOGY

SOP 10.

Scoring of Responses

Members receive a personal score for their response to each of the cases in a circulation. This is based on the final scoring of responses agreed by their peers at the Members Meeting.

Responses will be scored (taking account of the weighting given if there is a differential diagnosis offered) as follows, based on the discussion at the Members Meeting:

- 1 – Correct or acceptable response
- 0.5 – Responses that are incomplete or deficient or contain a minor error of no clinical significance
- 0 – Incorrect or no response

Therefore, in any circulation of 12 scoring cases, an ideal score for each participant is 12.

If a differential diagnosis is offered for a case but without any weighting being given for the different options, the differential diagnoses offered are assumed to be weighted equally for scoring purposes.

For a response to be considered correct there must be at least 80% agreement among members' responses on a correct diagnosis (including diagnoses judged acceptable), otherwise the case is considered unsuitable for EQA scoring purposes and each response is arbitrarily scored as 1.

An example of responses to a hypothetical case is given to illustrate the scoring, in particular where a member may have given a response with a weighted differential diagnosis.

Example of five different responses to a hypothetical case and their scoring:

Case: skin tumour on face, submitted as trichoepithelioma

Response no. 1

Trichoepithelioma

Response no. 2

Benign skin tumour

Response no. 3

Trichoepithelioma

Weighting 2

Basal cell carcinoma

Weighting 8

10

Response no. 4

Trichoepithelioma
Benign skin tumour

Weighting 5

Weighting 5
10

Response no. 5

Basal cell carcinoma

At the participants' meeting, at least 80% of responses give trichoepithelioma as the diagnosis, this response is judged correct and is scored 1.

Benign skin tumour is considered only partly correct and is scored 0.5.

Basal cell carcinoma is considered incorrect and is scored 0

Scoring of response no. 1

1

Scoring of response no. 2

0.5

Scoring of response no. 3

$(1 \times 2/10 = 0.2) + (0 \times 5/10 = 0) = 0.2$

Scoring of response no. 4

$(1 \times 5/10 = 0.5) + (0.5 \times 5/10 = 0.25) = 0.75$

Scoring of response no. 5

0

IRISH EQA SCHEME IN GENERAL HISTOPATHOLOGY

SOP 11.

Feedback to Members

When the final scoring for responses to a circulation is agreed, the Scheme Organizer or a member of the Steering Committee records the Minutes of the discussion about cases at the Members Meeting and the decisions taken regarding scoring of responses. The Minutes also record any other discussion or decisions taken at the Members Meeting, for example regarding SOPs. The draft Minutes are reviewed and agreed by a second person from amongst the Scheme Organizer and Steering Committee members. Based on this, the Scheme Organizer does the final marking of the members' Answer Sheets, The final marking is entered into the Scheme Database by the Scheme Administrator and checked by the Scheme Organizer. Members are then notified by email of the final listing of members' scores for the completed circulation, both in total and broken down case-by-case, with each member identified by PIN only. Those members whose responses fall in the bottom 2.5% of scores are identified.

The same mailing also includes a copy of the Minutes of the Members' Meeting and a copy of a personal Certificate recording participation in recent Scheme circulations and providing a record of points awarded for continuing medical education/continuing professional development activities. The mailing concluding a circulation should be sent out within four weeks of the Members Meeting.

Participation in the Scheme is part of a range of activities contributing to continuing medical education/continuing professional development. Participation in a range of such activities is prescribed by the Medical Council, whilst recording of such activities is undertaken by the Royal College of Physicians of Ireland, who will award CME points both to those members who submitted responses to a circulation (currently two points) and to those members who attended the Members Meeting (currently one point).

Participation in the Scheme is part of a range of activities that help to assure quality in histopathology reporting. Certificates of Participation in the scheme may be used as evidence of this activity for accreditation and other bodies or in any other appropriate context.

IRISH EQA SCHEME IN GENERAL HISTOPATHOLOGY

SOP 12.

Confidentiality

The Scheme Administrator gives Scheme members a confidential Personal identification Number (PIN) when they join the Scheme. The Scheme Administrator keeps both a paper list and computer database linking the members' identities and their PIN. The paper list is kept in a locked drawer and the computer database is password protected. The Scheme Organizer, Steering Committee members or any other pathologist participants do not have access to either the paper lists or the computer database. Members may request a change of PIN if there is a risk or evidence that their confidentiality has been compromised. Members may request a written re-notification of their PIN from the Scheme Administrator by mail or email, but the return re-notification of their PIN is sent by post.

All returned Answer Sheets from members are sent to the Scheme Administrator via email so that the possibility for identifying handwriting when assessing handwritten Answer Sheets is avoided. All pages of Answer Sheets should bear the member's PIN. The Scheme Administrator removes anything that might potentially identify completed Answer Sheets (e.g. envelopes or email addresses) before handing the completed answer sheets to the Scheme Organizer for the collation of responses. Therefore, the Scheme Organizer or Steering Committee members are not aware of the identity of the author of any response other than their own.

When required, any confidential communication to a Scheme member is passed to the Scheme Administrator in a sealed envelope bearing only the relevant member's PIN. The Scheme Administrator does not see the contents of the communication and the Scheme Organizer or Steering Committee members do not see the name of the recipient.

The Scheme Administrator only in the following two circumstances divulges the link between the name of a Scheme member and their PIN:

- In writing to that member when they request a re-notification of their PIN. PINs are not re-notified by telephone or email.
- In writing to the Scheme member in order to investigate appropriately a case of Persistent Substandard Performance when the Second Action Point is reached as defined below (see SOP 13)

IRISH EQA SCHEME IN GENERAL HISTOPATHOLOGY

SOP 13.

Persistent Substandard Performance

The United Kingdom Royal College of Pathologists (via their NQAAP for Histopathology incorporating the Steering Committee for Interpretive EQA) issues guidance regarding how persistent substandard performance in interpretive EQA schemes is handled, including diagnostic EQA schemes in histopathology. The Irish EQA Scheme in General Histopathology uses this guidance as a model for defining Persistent Substandard Performance (PSP) in the Scheme, with the Histopathology Working Group of the Faculty of Pathology taking on a governance role regarding PSP as defined below.

The principal aims of the Scheme, as with all similar schemes, are concerned with professional education and development and quality assurance. Furthermore, the gap between the structure of the Scheme and the material suitable for inclusion in the Scheme on the one hand and the structure and content of the real life workload of a histopathologist on the other is obvious but requires re-statement. Quality assurance in histopathology reporting and practice is a complex area and participation in an appropriate EQA scheme by histopathologists is but a small part of a wide palette of activities and practices which underpin quality in histopathology, guidelines for many of which are defined by the National Quality Assurance Program in Histopathology sponsored by the RCPI and Faculty of Pathology.

However, although it is likely to be a rare event, the Scheme has the potential to identify members who have a Persistent Substandard Performance with recurring markedly low scores as defined below. Although such Persistent Substandard Performance may have a variety of possible causes, the possibility that it might correspond (if sustained and otherwise unexplained) to poor performance in clinical practice must be considered. Therefore, appropriate and proportionate mechanisms need to be in place when Persistent Substandard Performance is identified.

Identifying Low Scores

In each circulation round, all members' responses are scored after discussion of cases at the Members Meeting. The final listing of members' scores for each circulation notes those members whose responses fall in the bottom 2.5% of scores. This is calculated by counting the number of responses to each circulation and calculating the number representing 2.5% of that figure, rounded to the nearest whole number. For example:

- If 56 pathologists respond to a circulation, 2.5% represents 1.4, rounded down to 1. The scoring mark that includes the lowest participant is identified and all those with that mark are considered to be in the lowest 2.5% for that circulation.

- If 84 pathologists respond to a circulation, 2.5% represents 2.1, rounded down to 2. The scoring mark(s) that include the lowest two participants is/are identified and all those with that mark are considered to be in the lowest 2.5% for that circulation.
- The Steering Committee retains the discretion to vary these rules to avoid clearly anomalous results (e.g. if all participants obtain an ideal score)

First Action Point

Any member can make occasional erroneous diagnoses, so the First Action Point for PSP is defined as occurring when a member has a score in the bottom 2.5%, as defined above, for two out of three successive circulations. The Steering Committee reviews the responses to the circulations in question of the member who has reached the First Action Point. A “Dear colleague” letter is sent anonymously to the member, reminding the member of the implications of reaching the First Action Point, as well as offering assistance and welcoming an explanation (see Addendum D), which is directed through the Chairman of the Histopathology Working Group of the Faculty of Pathology. The member is identified only via their PIN and the letter is handed to the Scheme Administrator for posting and verification that it has been received. Any correspondence from the member is received by the Scheme Administrator, personal identifying marks removed and the correspondence forwarded to the Chairman of the Histopathology Working Group .

When a member has reached the First Action Point, they must participate in the three subsequent circulations of the Scheme. Failure to participate in any of the three subsequent circulations is taken as equivalent to falling within the bottom 2.5% of scores for that circulation. This mandatory participation in the three subsequent circulations is set aside if there is verified confirmation of leave due to illness, sabbatical or maternity/paternity.

Second Action Point

The Second Action Point is reached if a member has a score in the bottom 2.5%, as defined above, for two out of three successive circulations that they have been obliged to participate in, having already reached the First Action Point (see above).

Outcomes following a Member reaching the Second Action Point

First, the Chairman of the Histopathology Working Group of the Faculty of Pathology will write to the participant (see Addendum E). The Chairman’s task is to determine whether the low EQA scores reflect low standards of routine practice that may put patient care at risk. An investigation will therefore review the responses in the circulations leading to the Second Action Point being reached, seek all possible explanations of the low scores (including a review of the nature of the EQA scheme itself) and concentrate on the participant's routine practice, including conditions of work. The emphasis will be on

identifying problems and implementing remedial measures rather than punitive action. The dialogue between the Chairman and the participant will be directed at reassurance that the participant is providing a high quality service and is not a danger to patients and should include:

- Evidence of valid participation in other EQA schemes, if appropriate
- Evidence of participation in quality assurance strategies in histopathology, including evidence of compliance with the National Quality Assurance Program in Histopathology guidelines.
- An assessment of workload, context and scope of practice

Although the member is identified by PIN only during the initial contact from the Chairman, it is required that the member directly identifies themselves during the course of this enquiry.

The Chairman of the Histopathology Working Group will discuss the findings of his/her informal investigation with available members of the Histopathology Working Group (a minimum of five) in such a way that will not reveal to the other members the identity of the pathologist under review. These steps should be completed with reasonable speed, a couple of months at most. If the Working Group is happy that a high quality service is likely being provided and that there is no significant risk that patient safety is being jeopardized, then a return to the scheme by the member with careful observation of performance is appropriate. In certain circumstances, a change in working scope or practice may result or it may be deemed that continued participation in a general EQA scheme (rather than a specialist scheme) is not appropriate.

If the majority of the Chairman and the consulted Working Group colleagues consulted are not satisfied of a reasonable explanation or if any lack of co-operation appears to be slowing the evaluation process, the Chairman will refer the pathologist on to the appropriate professional competence regulatory mechanisms of the Medical Council, which are currently being developed in conjunction with the statutory training bodies, including the Faculty of Pathology.

The latter procedures will be activated only in exceptional circumstances, i.e. when the Second Action Point regarding Persistent Substandard Performance is reached. This ought to be an extremely rare event and should cause no more concern to Scheme members than the current possibility of being reported to the Medical Council by a colleague for incompetence. The main purposes of diagnostic histopathology EQA schemes remain those of professional education and quality assurance in histopathology reporting. We hope and anticipate that appropriate EQA schemes will continue to be valued by histopathologists for this reason.

IRISH EQA SCHEME IN GENERAL HISTOPATHOLOGY

SOP 14.

Role of the Scheme Organizer

The Scheme Organizer co-ordinates the running of the Scheme. The role of the Scheme Organizer includes the following:

- Maintaining an archive of submitted cases, including a record of the submitting pathologist and specimen details for each case received
- Selecting a set of twelve cases for each circulation, potentially in conjunction with or replaced by member(s) of the Steering Committee.
- Arranging to have the twelve selected cases labeled, boxed and sent out to initiate the circulation
- Writing a letter to initiate each circulation that includes the time scale and relevant dates for each circulation, accompanied by an Answer Sheet
- Collation of responses to each circulation, with a summary listing for each case in a circulation of the offered diagnoses and their relative popularity.
- Oversight and organization of the Members' Meeting, including those responsible for leading scoring, voting and taking of Minutes
- Final marking, based on scoring agreed at the Members' Meeting, of Answer Sheets
- Liaison with the Scheme Administrator regarding communications and comments from Scheme members
- Handling of complaints from Scheme Members
- Production of an annual report on the Scheme's activity, furnished to the Board of the Faculty of Pathology and the Histopathology Working Group
- Responsibility to the Histopathology Working Group of the Faculty of Pathology and the Board of the Faculty of Pathology, in conjunction with the Steering Committee for the ongoing effective operation of the Scheme

Role of the Scheme Administrator

The non-medical Scheme Administrator is IEQAS. IEQAS maintains the confidentiality of the link between the name of a Scheme member and their individual PIN (see SOP 12) and facilitates the efficient functioning of the Scheme. The role of the Scheme Administrator includes the following:

- Maintenance of a database (paper and computerized) of members
- The database links the identities of Scheme members and their details (including contact details, email address and any sub-specialty areas they wish to be excluded from their repertoire of practice) with an individual, confidential Personal Identification Number (PIN)
- Retaining completed Scheme Membership Forms

- Assigning PINs to new scheme members and re-notifying (if requested) in writing members of their PINs
- Labelling, assembling into boxes and sending out boxes of slides for each circulation.
- Sending the email notification from the Scheme Organizer to members when a circulation is initiated
- Sending an email reminder on the specified handover date to the nominated pathologists in those laboratories that share a slide box
- Sending an email reminder to members two weeks before the final date for submitting responses, including a list of members PINs who have already responded
- Handling received Answer Sheets with a check for completeness and problems, removal of identifying details and collection and printing for handover to Scheme Organizer
- Entering a record of receipt of Answer Sheets on to the database and sending an email acknowledgement to each member
- Sending an email from the Scheme Organizer in advance of the Members' Meeting with a summary listing of the responses and their relative popularity, a list of those members PINS who responded and notification of the Members' Meeting
- Sending an email from the Scheme Organizer to scheme members with the final scoring of responses and minutes of Members' Meeting
- Sending via email personal certificates of Participation at the end of each circulation, recording participation in recent circulations of the Scheme by the relevant member and including a record of CME points awarded for participation in the circulation (2 points) and attendance at the Members Meeting (1 point)
- Handling of confidential communications between Scheme members and the Scheme Organizer and/or Steering Committee
- Handing on comments or complaints from Scheme members to the Scheme Organizer
- Sending an email requesting cases to Scheme members in rotation
- Maintenance of the histo@ieqas.ie email address, checking the mailbox at least once every two weeks (every week during the period of a circulation)

Legal Responsibilities of the Scheme Organizer, Scheme Administrator, Steering Committee Members and Scheme Participants

The Organizers, Administrator and Participants of the Scheme owe no duty of care in the organization, administration, carrying on or membership thereof or howsoever to any other Organizers, Administrator or Participant thereof and no liability shall attach to any Organizers, Administrator or Participant carrying on membership of the Scheme to any other Organizers, Administrator or Participant carrying on membership thereof.

IRISH EQA SCHEME IN GENERAL HISTOPATHOLOGY

SOP 15.

Communications & Complaints

All written or email communications from members to the Scheme Organizer or Scheme Administrator will be stored in a file for a minimum of five years.

When a telephone or verbal communication is made, the Scheme Organizer or Administrator receiving the communication will make a written note summarising the communication and that will be dated and stored in the file.

Where the communication may be construed as a complaint, the action taken to remedy the complaint will be recorded and dated and clipped to the original communication in the file. Complaints will be answered within two weeks if possible.

If the Scheme Organizer judges the complaint to be justified and of a nature which requires any alteration in the procedures of the scheme, the preferred sequence of events for enacting such changes would be:

- Production of a draft revision to the relevant SOP and circulation to Scheme members by email.
- Discussion at the Members Meeting
- Notification to the Histopathology Working Group of the Faculty of Pathology of the proposed revision.

The Scheme Organizer may wish to raise complaints at a Members Meeting. If so, the Scheme Organizer will try to maintain the anonymity of the complainant. If the matter is confidential, the complainant should use his/her PIN as a means of identification and communicate via the Scheme Administrator.

A structured report is provided annually by the Scheme Organizer detailing the operation of the Scheme during the year, as well as the details of any complaints and revisions to the Standard Operating Procedures. This report is sent to the Board of the Faculty of Pathology, the Histopathology Working Group and the Steering Committee of IEQAS.

Retention of Material & Records

The Scheme Organiser keeps at least two full sets of slides from each Circulation for a period of ten years at least.

The Scheme Organizer hands over scored copies of members' Answer Sheets to the Scheme Administrator and these are kept for a period of ten years at least.

All other communications from members (including a written note summarising telephone or verbal communication and printed emails) are kept for a period of ten years at least by the Scheme Administrator.

