Scotland and Northern Ireland EQA Scheme in General Histopathology

EQAQ01

QUALITY MANUAL

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Feb 2021	9.4	6 Pages (Front, 5, 6, 7, 12 & 24)	Updated: location of copies (front pg), scheme secretary email address (Pg5), organisation chart (Pg6), QM qualifications (Pg7), scheme committee chart (Pg12), responsibilities table (Pg24).

Table of Contents

1 INTRODUCTION

This document, together with specified Standard Operating Procedures (SOPs) and template letters, represents the Quality Management System of the Scotland and Northern Ireland EQA Scheme in General Histopathology. It has been compiled to meet the requirements of the International Standard ISO/IEC 17043:2010(E) and all other appropriate national and international standards. All procedures specified herein are mandatory within the Scotland and Northern Ireland EQA Scheme in General Histopathology. This Quality Manual will be reviewed annually.

2 SCOPE OF ISO 17043:2010(E)

This International Standard specifies general requirements for the competence of providers of proficiency testing schemes and for the development and operation of proficiency testing schemes. These requirements are intended to be general for all types of proficiency testing schemes and have been used as a basis for the specific technical requirements of this scheme.

3 TECHNICAL REQUIREMENTS

3.1 General Information

The Scotland and Northern Ireland EQA Scheme in General Histopathology is based within the Pathology Department, in the Surgical Directorate, Ninewells Hospital, Dundee.

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Details of the scheme, including current operating procedures, can be accessed at:
http://www.pathology.scot.nhs.uk/resources/pathologists-eqa/

A brief summary of the Scotland and Northern Ireland EQA Scheme in General Histopathology is as follows:

Between 120 and 140 Consultant Pathologists from departments in Scotland and Northern Ireland are assessed bi-annually on their diagnoses of 10 general histopathology slides. Four optional additional cases of special educational interest are also circulated, but not marked. The slides are provided for each circulation by two members of the scheme's Management Committee on a rotational basis. The cases are chosen to emulate general histopathology in routine practice.

A personal score is provided for each participant for each circulation in the form of an anonymised spreadsheet listing participants by confidential personal code numbers. Individual performance is monitored over time for consistency. Confidentiality is maintained throughout. Only the Scheme Secretary and Data Administrator can be aware of results of individuals, except under circumstances of consistent poor performance, when action from the Chairperson is required.

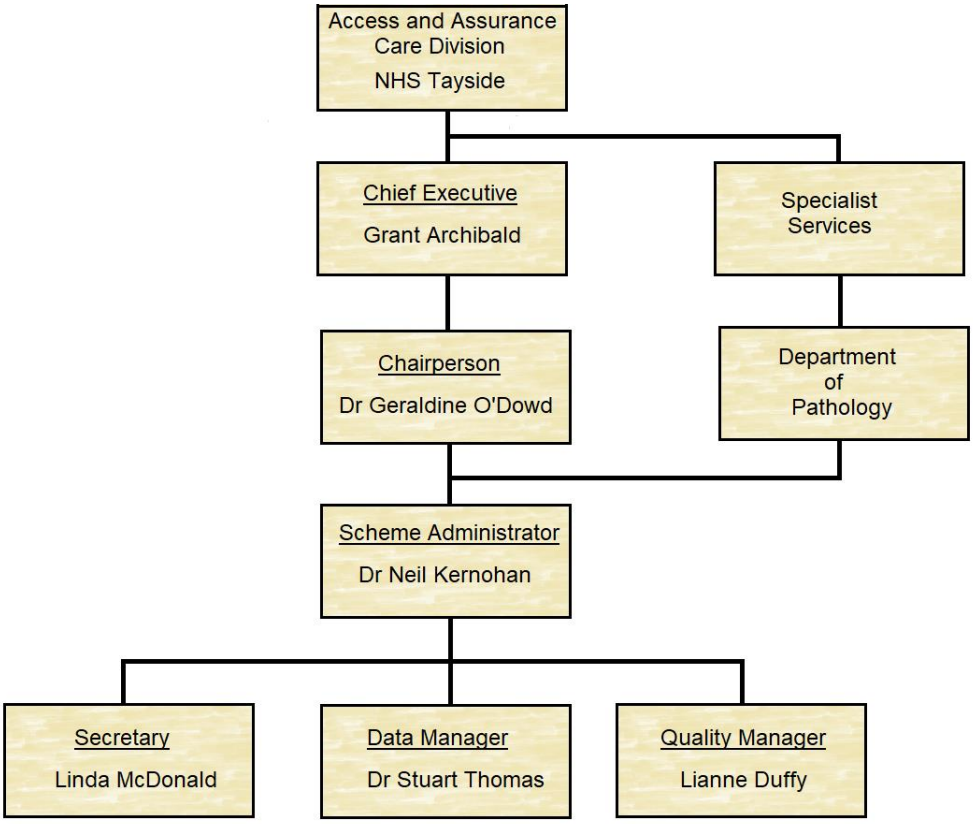
The scheme has two main aims:

1. An educational process for the Continuing Professional Development of Consultant Pathologists.
2. A method of auditing and monitoring the consistency and accuracy of diagnosis throughout Scotland and Northern Ireland.

Funding for the scheme and its supervision is covered by a renewable grant from the Scottish Executive (National Services Division). This grant has been placed on a three yearly rolling programme with annual reviews. The introduction of fees for non-Scottish participants was initiated in 2015/16.

3.2 Personnel

The Scotland and Northern Ireland EQA Scheme in General Histopathology is based in Dundee within Ninewells Hospital Pathology Department within the Specialist Services Section of the Access and Assurance Care Division of NHS Tayside. The organisational relationships are shown below:



Responsibilities can be summarised as follows:

Officer	1st level line management: Responsible to	2nd level line management: Responsible to
Dr Geraldine O'Dowd	NHS Tayside	NSD
Dr Neil Kernohan	Dr Geraldine O'Dowd	NHS Tayside
Dr Stuart Thomas	Dr Neil Kernohan	NHS Tayside
Linda McDonald	Dr Neil Kernohan	NHS Tayside
Lianne Duffy	Dr Neil Kernohan	NHS Tayside

The Scheme Chairperson is responsible to the funding and monitoring bodies of the scheme, namely the Scottish Executive (National Services Division) through NHS Tayside. The Scheme Administrator is responsible to the Scheme Chairperson.

Significant decisions made by employees of the scheme included in the above chart are to be ratified by the Management Committee. This committee consists of the Scheme Chairperson, Scheme Administrator, Scheme Secretary, Quality Manager, Data Manager, Northern Ireland Consultant Pathologist representative and eight rotating Consultant Pathologists who are also current scheme participants.

The post of Chairperson is available for re-election every 3 years, whereas the post of Scheme Administrator is permanent. Eight participant members change on a rotational basis, with participants remaining on the committee for 4 meetings (during which time they provide both assessable and special educational cases).

The posts of Scheme Secretary, Data Administrator and Quality Manager will be held by individuals having the necessary qualifications and expertise in their specific areas. Both competencies and training events for these staff will be recorded.

Aside from the sub-heading below, Professional Direction, the personnel procedures outlined relate only to the permanent members of the Executive Team. Most of these procedures are integrated into those of the host organisation, namely the Pathology Department at Ninewells Hospital and Medical School, so that the document codes provided below relate to generic departmental Standard Operating Procedures.

The Scheme Chairperson is guided by similar procedures established by her employer.

3.2.1 Professional direction

Professional direction is essential for the proper performance of an EQA scheme, and for ensuring accountable and informed objectives and decision making.

3.2.2 Management Committee

Management Committee Member	Professional Qualifications
Scheme Chairperson	B.Sc (Hons.), M.B., Ch.B.(Hons.), F.R.C.Path
Scheme Administrator	B.M.Sc, M.B., Ch.B, F.R.C.Path
Management Committee clinical members	All are Consultant Pathologists employed by accredited departments within Scotland and Northern Ireland
Data Administrator	BSc Med. Sci. PhD, MB, ChB
Quality Manager	MIBMS, IBMS Certificate of Extended Practice in Quality Management, Quality Management Experience
Scheme Secretary	Secretarial Experience

3.2.3 Professional Organisations

The Management Committee is guided professionally by NSD, the Royal College of Pathologists, NQAAP and the Institute of Biomedical Scientists.

3.2.4 Staffing

Staff are an important asset to the effective running of the scheme.

Staff records of the permanent Executive Team members (Scheme Secretary, Quality Manager and Data Administrator) are kept within personal files and on Q-Pulse. Full access is only available to the Pathology Department Clinical Team Manager and the Database Administrator. Partial access is given to individuals as necessary, e.g. Training Officers etc. Medical staff records are kept by Medical Staffing as per NHST Policy.

Training needs are established as part of the Performance Review process Ref. **EQAM03**

3.2.5 Temporary Staff

No temporary staff will be employed in the running of the scheme. If one of the members of the executive team suffers long term absence, other members will deputise as follows:

Post Holder	Deputy
Chairperson	Administrator
Administrator	Chairperson
Secretary	Quality and Data Managers
Quality Manager	Data Manager and Secretary
Data Manager	Quality Manager

3.2.6 Personnel management

Personnel management ensures that all staff contribute fully and effectively to the service, whilst receiving fair and consistent treatment from management.

This standard is fulfilled by the following Pathology Department and specific EQA procedures:

MAA002	Training and Development Policy for Non-Medical Staff
EQAM04	Induction, Training and Staff Selection
EQAM03	Performance Review Procedures
MAA014	Staff Job Descriptions
	NHS Tayside General Policies on Staff Development and Employee Relations

3.2.7 Inductions

Staff Orientation: A comprehensive orientation and induction programme is an important element in the introduction of new permanent members of staff Ref**: EQAM03.**

Departmental Induction: The content of the induction programme is detailed in **EQAM04**. Records of staff orientation and induction are kept in the individual's training portfolio and staff record folder.

NHS Tayside (NHST) Induction: An NHST induction is also completed, the content and records of which are also kept in the staff record folder.

3.2.8 Job descriptions and contracts

Written job descriptions and contracts enable staff to know their duties, responsibilities, and rights. Each member of staff has a job description prepared using Pathology Department **MAA014**. Copies are kept on the local G: drive and the individual's staff record folder. Review of the job description forms part of the performance review process.

The Access and Assurance Care Division - Human Resources Department, issues Contracts of Employment directly to the staff member, copies of which are kept in staff record folders.

3.2.9 Authorisation of staff

Only individuals who meet the minimum specifications described in the Job Specification will be employed by the scheme. Once all training has been completed and competencies have been signed off, staff members will be deemed to be authorised to carry out their duties within the scheme.

Authorisation of various activities can be summarised as follows:

Activity	Authorisation
Selection of appropriate proficiency test items	Scheme Management Team
Planning of any additional testing schemes	Scheme Executive Team
Performing particular types of sampling	Sub contracted departments
Operation of specific equipment	Relevant executive team members
Conduct measurements to determine stability, homogeneity, assigned values and uncertainties of the test items	Scheme Management Team
Prepare, handle and distribute proficiency test items	Scheme Executive Team, particularly the scheme secretary and deputy
Operate the data processing system	Data Administrator and deputy
Conduct statistical analysis	Data Administrator and deputy
Evaluate the performance of proficiency testing participants	Scheme Management Team
Give opinions and interpretations	All scheme participants
Authorise the issue of proficiency test reports	Scheme Administrator and deputy

3.2.10 Staff Annual Joint Review

Achievement of EQA Scheme and personal objectives is facilitated by regular staff appraisal. Ref: **EQAM 03.**

It is the responsibility of the Scheme Administrator or Scheme Quality Manager to carry out appraisals of the permanent Executive Team members, excluding the Chairperson. Appraisals of the Scheme Administrator and Scheme Chairperson in relation to EQA Scheme duties are incorporated into their main post appraisals, carried out by their appraisers at their respective places of employment.

The Scheme Secretary and Quality Manager participate in an annual joint review specific to the EQA Scheme, (**EQAM03**). This is distinct from any other reviews that they may participate in relating to other duties/posts.

The EQA reviews include consideration of:

- the stated quality objectives and plans of the scheme
- the current job content
- documentation of training needs and agreed personal objectives with the appraiser
- evidence of individual action if personal objectives are not met
- evidence that management has recognised the agreed development needs of individual staff members

All staff participating in annual joint reviews have received appropriate training.

Records of all Executive Committee EQA-specific joint reviews are kept in individual personnel files.

3.2.11 Staff meetings

Regular staff meetings are a mechanism for maintaining good communications and disseminating information on all aspects of the laboratory service.

The Executive Team meets on a regular basis throughout the year. These meetings are to discuss relevant significant 'marker posts', such as the Management Review, Management Team Meetings, Annual Report, reports to NSD etc. Those members of the Executive Team based at Ninewells Hospital meet on a monthly basis for general progress reports.

3.2.12 Staff training and education

Access to continuing education and training is important for all staff and participation in Continuing Professional Development schemes is supported as a method of achieving this for relevant members of the EQA Team.

There is a training and education programme for all members of staff (Pathology Department ref. **MAA002 to MAA010 and EQAM04**).

Training and education shall be in accordance with guidelines from the relevant professional and registration bodies. All staff shall be given the opportunity for further education and training in relation to the needs of the scheme and their professional development.

Andy Munro, is the Departmental Training Manager, based in the Pathology Department, available to permanent EQA Executive Team members.

There are resources for training and education that include:

- access to library and information services
- access to a conveniently situated quiet room for private study
- staff attendance at meetings and conferences
- financial support

Records of all training and education are kept on Q-Pulse. A training and development portfolio exists for each member of staff.

3.3 Equipment, Accommodation and Environment

3.3.1 Procurement and Management of Equipment

The proper procurement and management of equipment ensures that the laboratory can fulfil the needs and requirements of users.

The Scheme Administrator ensures that equipment, (the requirement for which is monitored by the Scheme Secretary), is sufficient and appropriate to provide the service.

3.3.2 Procedure

For generalist equipment such as the Scheme's computer or slide transportation boxes, there is an NHS Tayside procedure for the procurement of equipment: [NHS Tayside Standing Orders Section B: Competitive tendering] this includes selection and acceptance of quotations and tenders.

Documentation relating to other aspects of equipment procurement is found in **EQAM08** and Pathology Department **MAA015** and covers the following areas: -

- assessment and justification of need
- selection and acceptance
- training, (if provided by manufacturers, is part of the specification)
- maintenance, service and repair
- planned replacement and disposal
- record of equipment failure and subsequent corrective action

This type of equipment is procured for the Scheme by the Pathology Department.

Minor equipment such as small furnishings or stationery is ordered directly by the Scheme Secretary on the approval of the Scheme Administrator.

3.3.3 Inventory

An inventory of significant equipment, namely the scheme computer, printer and microscopes is held in **EQA Form 12** within Q-Pulse and covers:

- name of manufacturer
- serial number
- date of purchase or acquisition
- record of contracted maintenance
- Record of equipment downtime

Records of equipment electrical safety checks are held by Medical Physics at Ninewells hospital and by the Estates department at Perth.

3.3.4 Accommodation

A department requires sufficient space to ensure that work is performed safely and efficiently.

The Pathology Department in which the EQA Scheme office is housed underwent a significant upgrade in 2004, which allowed re-location of the EQA office and made better use of the available space. VDU and general Risk Assessments will take place regularly.

The upgrade also helped the EQA scheme in terms of providing improved space for:

- the functioning and use of all equipment
- separation of incompatible activities
- facilities for staff
- facilities for storage
- Facilities for sample packaging and distribution
- Potential future developments

An NHST Security Policy is administered by site managers. Visitors are asked to report to the General Reception on arrival.

Access to the EQA office area is restricted to authorised personnel via a coded lock. The office is also locked when not in use.

3.3.5 Facilities for staff

The premises have staff facilities that are readily accessible and include:

- sufficient toilet accommodation
- shower facilities and rest areas
- safe and secure working arrangements
- basic catering facilities & drinking water supply
- changing area and secure storage for personal effects

3.3.6 Facilities for storage

The provision of sufficient storage space, under the correct conditions, is important in maintaining the integrity of samples and records.

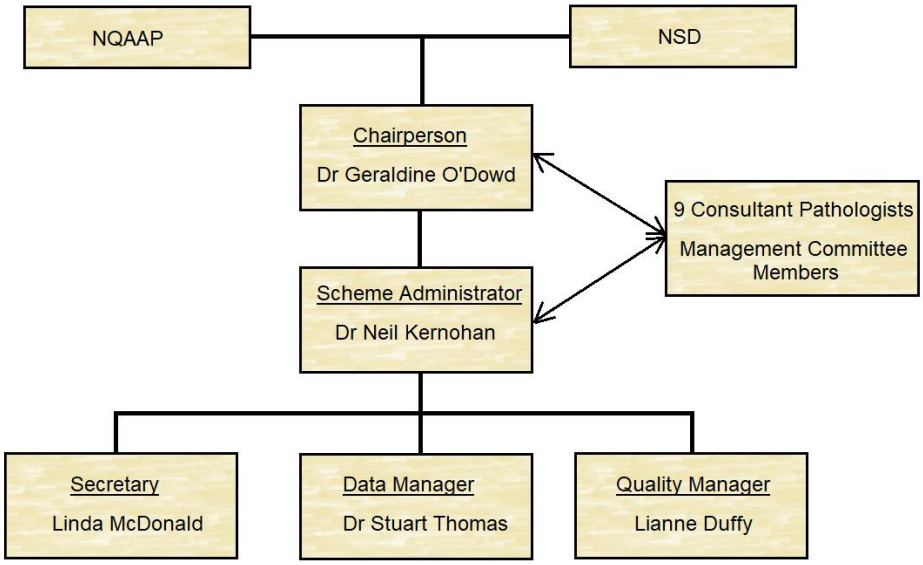
Storage facilities are described in procedure **EQAM02**. Slides and documents relating to the current circulations are locked securely within the scheme office. Archived paper documents and slides are retained within a locked wardrobe cabinet.

The storage facilities are in accordance with all relevant legislation, regulations and guidelines.

3.4 Design of the Scheme

The EQA Scheme shall be directed by an organiser with appropriate scientific training, authority, resource and experience in the field of operation.

It is recognised within our scheme that the Chairperson and Administrator will be fully qualified consultant histopathologists operating in a fully accredited department.



The EQA Scheme Management Committee membership is divided into two elements, namely:

- Executive Team: This comprises the Chairperson, the Scheme Administrator, Scheme Secretary, Data Administrator and Quality Manager.
- Clinical Committee Members: Apart from the Northern Ireland representative, the remaining members are temporary, usually remaining on the Committee for 4 meetings, during which they provide half of the slides for one Circulation. There are generally 8 of these members at any one time, and all are Consultant Pathologists currently participating in the scheme, and who are employed by Accredited Departments.

Meetings of the full Management Committee are twice per year, to coincide with the provisional results stage of each slide circulation.

The Executive Team meets regularly throughout the year and at least every 2 months. These meetings are to discuss relevant significant 'marker posts', such as the Management Review, Management Team Meetings, Annual Report, reports to NSD etc.

The EQA Scheme is integrated in to the Pathology Department and NHS Tayside Structure in terms of provision of appropriate Health and Safety procedures. Andrew Moultrie (Mortuary Manager) is the departmental Health and Safety Officer.

The EQA Scheme is planned, designed and run to meet clear objectives to assess and maintain an acceptable level of service.

3.4.1 Description of scheme

EQAO01 is a document describing the Scheme. Copies of all SOP's are available on the Scheme website: **http://www.pathology.scot.nhs.uk/resources/pathologists-eqa/** of which all new participants are informed.

3.4.2 External professional advice

It is essential that the EQA Scheme has procedures for regular external review of the service provided and its objectives.

3.4.3 Communication with the National Quality Assurance Advisory panel (NQAAP)

Copies of the Annual Report for the Scheme as well as the annual Management review are sent to NQAAP as a formal communication arrangement. Reports are also sent to NSD and UKAS.

3.4.4 Modifications to the Scheme

The EQA Management Committee approves changes in EQA scheme design, including the introduction of new procedures and the cessation of existing procedures. These changes are either proposed by clinical members of the Management Committee, or the Executive Team as a result of:

- Management Review
- Internal or external audit
- Executive Team Meetings
- User surveys
- Requests or suggestions from external bodies, such as UKAS, NQAAP and NSD

3.4.5 The Participants

Participants meet twice per year, on a voluntary basis, via attendance at Participant Meetings or via Teams. These meetings coincide with the release of provisional results, which are discussed with the Management Committee members who have provided the slides for the relevant circulation. Ref: **EQAO06.** The Scheme Chairperson also attends these meetings, and participants have the opportunity to raise any issues pertinent to the scheme. The above meetings are at Scottish hospitals on a rotational location basis.

The geographical distribution and numbers of participants shall be such as to maximise the effectiveness of the EQA Scheme.

Participation in the Scheme is open to all Consultants in Scotland and Northern Ireland, along with pathologists who have the authority to report independently. Ref: **EQAO02**.

The number of participants per circulation averages between 120 and 140, which is sufficient to ensure statistically meaningful evaluations of performance.

The scheme would hold an extra ordinary executive meeting to discuss a plan of action if participating numbers fell below 120.

3.4.6 Description of arrangements for participation

Arrangements for participation, including confidentiality, are included in the General Description of the Scheme and in the Operational Standard Operating Procedures (**EQAO01** and **EQAO02 - 09**), all of which are available to all new participants on the Scheme website at http://www.pathology.scot.nhs.uk/resources/pathologists-eqa/

3.4.7 EQA Scheme design: sample distribution and analysis of results

The nature and numbers of samples distributed and a valid design and analysis of the results are key features of an effective EQA Scheme.

The nature of the cases selected reflects the clinical service delivered by the participants. This is achieved as follows:

- Cases for assessment are submitted on a rotational basis by members of the Management Committee and/or the Scheme Chairperson and Scheme Administrator. The cases are representative of the routine general histopathology workload and do not include bizarre or controversial cases. Cases come from laboratories which are accredited and which perform satisfactorily in a relevant technical EQA Scheme. The four cases of special educational interest are identified separately, also by members of the Management Committee.

- The 10 assessment cases for each circulation are chosen from an original 20, after all Consultants on the Committee have provided diagnoses for these. The diagnoses are anonymised, and evaluated by the Committee, thereby enabling selection of the 10 most suitable cases. This Standard is covered by **EQAO03**.

3.4.8 Evidence for validity of the scheme design and the evaluation of performance

Procedures **EQAI01** and **EQAO03, 04, 05** ensure that:

- There is a clear description of methods for assigning values to participant diagnoses. The completed response forms are marked by the two lead Management Committee members according to the agreed marking already approved by the full Management Committee. The marking system is as follows: correct answer – 1 mark; answer with minor diagnostic error – 2 marks; answer with major diagnostic error likely to affect patient management – 3 marks. For each round, therefore, a perfect response would attract a score of 10 marks. However if in any circulation the consensus i.e. correct diagnosis for any slides is not achieved by 80% of respondents then the slide would be removed from that circulation for scoring purposes.

- There are procedures for calculating the dispersal of results among participants and for identifying outliers. A listing is prepared recording the total number of participants in the circulation, individual scores per case and total score for the circulation. This document and the marking exercise are then considered by the Management Committee and any amendments made. A provisional results sheet for the circulation is sent to each participant prior to discussion and final agreement of the marking at the appropriate Participants Meeting.

- Evidence for panel approval of results is recorded in minutes of the Management Committee meeting held after release of each set of provisional results. The meeting includes discussion of the individual and overall performance in respect of the cases which have been circulated in the last EQA round, and the review and necessary amendment to the participant scores prior to issue to participants of the provisional results sheet for the circulation under consideration.

- Cases and anonymised responses are also discussed and re-evaluated, with those participants who wish to attend, at the Participant Meetings. These meetings follow release of the provisional results, and are attended by the Chairperson, as well as those members of the Management Committee who have submitted cases for the circulation being discussed.

- An Annual Report, including high level data, is sent to NQAAP, for which feedback is received. This Annual Report, along with a summary of the Management Review is also presented at the annual meetings with National Services Division, (the scheme's funding body). Minutes of these meetings are retained in the scheme office.

3.4.9 Assessment and evaluation of performance

An assessment and evaluation of performance is a key educational function of EQA Schemes.

3.4.10 Participation criteria

There are documented and defined participation criteria within procedure **EQAO02.** The Scheme is available to those who report surgical pathology cases and have the authority to report independently on material which is part of the Scheme i.e. consultants, and specialty trainees post MRCPath who have achieved their CCT and are reporting independently. Trainee specialty trainees may take part at the discretion of the executive team but they will not be scored and therefore not be subject to action for "persistent substandard performance".

If the participant does not routinely report certain categories of surgical pathology cases (e.g. gynecological cases) then this should be notified to the Administrator either on joining the Scheme, or when circumstances change and prior to receipt of the current circulation, and such cases will be excluded for scoring purposes.

No more than three sub specialties will be accepted and this should affect the marking of no more than three of the diagnostic cases in any individual run, therefore at least seven diagnoses must be given on each return. If no indication of "opting out" is given on the answer sheet then the diagnosis given will be marked, and that mark included in the results.

When a participant is away from work for a protracted period (e.g. sabbatical, maternity leave) then he/she should inform the Administrator so that their participation can be suspended.

3.4.11 Performance Criteria approval

The Scheme's performance criteria were approved by NQAAP, by NSD and by CPA at the time of the Scheme's inception. The scheme currently holds UKAS accreditation. Any significant proposed revisions are put forward by the Management Committee to the above bodies for approval.

An Annual Report is submitted each Calendar Year to NQAAP and NSD to demonstrate current performance data.

3.4.12 Definitions and procedures for acceptable performance

Procedures **EQAO04, 05, 07 and EQAI01** provide definitions of acceptable performance for individual participants.

The Scheme aims to identify any member showing a persistent substandard performance in accordance with the recommendations of the National Quality Assurance Advisory Panel (NQAAP), Joint Working Group on Quality Assurance (Histopathology/Cytopathology).

After the calculation of the personal scores for each circulation, a database query ranks and sorts the participants' scores. A defined percentage, currently 2.5%, is used to identify participants at the bottom of the ranking. If the number of participants in the '2.5% group' consists of more than 5% of the total number of participants in the circulation, the lowest score in the '2.5% group' will be excluded and this will continue until the group comprises 5% or less of the total participants, even if this is less than 2.5%.

Any participant within this group for the current circulation, but not in either of the preceding two circulations, receives informal notification of this in writing from the Scheme Chairperson, reminding the participant of possible implications of this in relation to scores for the next two Circulations. This letter, referred to as the "2.5% Notification Letter" is identified by the participant's code number only and is produced from an existing template by the scheme secretary for posting to the relevant participant.

A participant is considered to be a "persistent substandard performer" if their total score for a circulation falls in this 2.5% group and thereafter remains at this level in one of the next two circulations. In each circulation, each participant is informed of their score and whether it is within the 2.5% group.

If a persistent sub-standard performer is found, the First Action Point is triggered. The Chairperson of the Management Committee sends a "First Action Point" letter to the participant, highlighting the issue, offering appropriate advice and assistance and informing the individual that if their score falls within the 2.5% group in two out of the next three circulations, then the "Second Action Point" is triggered and the Chair of the Professional Performance Panel is informed and will then initiate an investigation. (Ref: "Principles and Guidance for Interpretive External Quality Assessment Schemes in Laboratory Medicine".) NHS Tayside also have their own "Statutory Duty of Candour" where relevant. It is also made clear that for the next three circulations, a failure to participate without good cause agreed by the Chairperson will be considered equivalent to a score in the 2.5% group.

Procedures then follow a series of action points, triggered by the pattern of response to communications and subsequent performance by the participant. The procedures increase in 'severity' leading through to such cases where the Chairperson of the Management Committee becomes concerned that the performance of a participant gives cause for concern such that the quality of patient care may be in doubt. Here the Chairperson is entitled to bring this to the attention of the Chair of the Professional Performance Panel even if the numeric criteria for persistent substandard performance have not been fulfilled. In this event, the data relating to the participant is discussed by the Management Committee when appropriate action will be decided.

3.4.13 Recording of actions taken in relation to performance

All actions are recorded and retained securely as follows:

- Computer copies of outgoing correspondence with the Scheme Chairperson.
- Paper copies of all correspondence, including incoming responses, in a lockable security box as detailed in **EQAM02**, kept within the EQA Scheme office.

3.4.14 Sub-contractors and collaborators

No elements of the EQA Scheme are currently contracted out, apart from the provision of test slides. All contributing departments must be accredited, as described in **EQAO03**.

If any other element of the EQA Scheme (for example, packaging and distribution, statistical analysis of results) is contracted out, it is important to ensure that it is controlled so as not to compromise the effectiveness of the service.

3.4.15 Preparation of test items

It is essential that the quality of the test items used in EQA Schemes in laboratory medicine is sufficient to meet the demands of the service.

3.4.16 Accuracy of test items

The EQA slides are sections taken from actual clinical case material. The slides seen by participants are checked individually by the lead Management Committee Pathologist to ensure that they all have similar diagnostic features.

3.4.17 Ethical considerations

The material used for EQA slides is all of human origin, and due regard is paid to ethical considerations. This relates principally to the issue of anonymity, confidentiality and control of technical material (as defined in procedures **EQAO03, 04, 05, 07** and **EQAM02**) which ensure that:

- Slides are coded with numbers, not patient names, and are thereby anonymised.
- Slides are seen only by participants, trainees and Management Team members.
- All slides circulated to participants are labeled with a unique identifier and all returns recorded to enable tracing of missing slides.

3.4.18 Process of slide manufacture

Occasionally, slides are generated by participants within the host organisation, namely when a departmental member is on the Management Committee. In this circumstance slides are prepared using departmental procedures **LHM003**, **LHM004** and **LHM006**, which define procedures for all stages of manufacture of the slides, including process controls and documentation of batch manufacture.

Other slides are prepared using similar procedures at the other laboratories, who must be accredited and are involved in the scheme.

3.4.19 Uniformity, stability and shelf life

Slides are retained securely within the EQA Scheme storage system for a period of 10 years (**EQAM02**), which is a period less than that at which quality may start to decline.

3.4.20 Statistical Analysis

The scores are analysed and presented on a Provisional Results spreadsheet by the Data Manager to present to the Management Committee for their approval. Any amendments are incorporated and the provisional results sent to participants to identify their scores clearly and compare their score with the (anonymised) scores of others, prior to final approval at the ACP Meeting. The Data Administrator then amends the data as necessary following the ACP Meeting, after which the final results are printed off for distribution. These final results include a summary of individual scores over the current and previous circulations in order that performance over time may be monitored.

All stages of data entry are checked for error by the Scheme Secretary. These procedures are documented in **EQAI01** and **EQAO04**, **EQAO05** and **EQAO07**.

The success of an EQA Scheme depends critically on a timely and accurate entry and analysis of participants' results.

3.4.21 Validation of data entry

EQAI01 defines the procedure for validation of data entry, including double-checking of scores on each paper pro-forma, and double-checking that scores have been correctly inputted into the computer system.

3.4.22 Outliers, non-analytical errors & results expressed in non-standard or inconsistent units

EQAO04 Defines the procedure for giving participants the opportunity to rectify errors or inconsistencies that do not relate to professional judgment, for example the submission of two photocopies of one side of a completed pro-forma, in the absence of the other side.

The Management Team strives to ensure that participants are given every opportunity not to be penalised for such errors.

Any suspicion of collusion however, will be fully investigated by the Executive team and their findings discussed within the Management team. Proven concerns can then be raised with NQAAP and NSD.

3.5 Choice of Method or Procedure

Participants are assessed bi-annually on their diagnoses of 10 circulated general histopathology slides. Four optional additional cases of special educational interest are also circulated, but not marked.

The slides are provided for each circulation by two members of the scheme's Management Committee on a rotational basis and are examined by the participants within their own department. The cases are chosen to emulate general histopathology in routine practice.

3.6 Operation of the Scheme

3.6.1 Arrangements for participation

It is important that participants are informed about the details of the EQA Scheme and their rights and responsibilities, as described in section 'Communicating with Participants' of this manual.

3.6.2 Management of materials

It is essential to have proper management of all materials.

Slides are the only materials utilised by the Scheme and the management of these is described in Procedure **EQAM02**.

3.6.3 Packaging and accompanying documentation

The participant must receive EQA samples that are correctly and safely packaged and with clear instructions for their use and the return of results.

3.6.4 Batch integrity

Procedure **EQAO03** documents procedures to ensure the integrity of batches of EQA slides.

A sufficient number (currently 30 sets) of the selected slides with relevant clinical information is assembled by two members of the Management Committee in order to provide one set for each cluster and several spare sets. These are sent to the Scheme Secretary. Special educational cases, which are not used for scoring, are generated and identified separately, with 30 sets provided.

Slides are labelled by the Committee member providing the current batch with an original laboratory number, which ensures the correct samples are distributed. The Scheme Secretary ensures all slides are then labelled with a unique identifier to ensure an audit trail of slide distribution is feasible.

3.6.5 Packaging and distribution

Slides are packaged and distributed in accordance with departmental procedure **LHM006** (Slide Labelling and Quality Assurance), which enable the safe transport without danger of injury to those transporting or opening the packages.

Slides are posted by Recorded Delivery to ensure traceability during transit.

3.6.6 Information enclosed with slides in transit

Slides are sent to participants are accompanied by the following supporting information:

- A pro-forma with case histories for completion of diagnoses.
- A distribution list of participants in the relevant department, and details of onward transmission to other departments if required.
- A letter (**EQA Letter 06**) informing of procedures for the handling of the test slides and dates for return of slides and diagnoses.

3.7 Data Analysis and Records

3.7.1 Management of data and information

The proper management of data and information in the laboratory is essential for the provision of the service.

3.7.2 Availability of data

Pathology Laboratory management in conjunction with the Computer Services Unit ensures the availability of data and information required to provide a service that meets the needs and requirements of users, including those within the EQA Scheme. The scheme Data Manager is the point of contact for the Scheme Administrator and Scheme Secretary for such matters.

3.7.3 Performance Criteria

There are qualitative and quantitative performance criteria for each circulation. These are documented in **EQAO04, 05 & 07** and **EQAI01**. The completed response forms are marked by the two lead Management Committee members according to the agreed marking already approved by the full Management Committee. The marking system is as follows: correct answer – 1 mark; answer with minor diagnostic error – 2 marks; answer with major diagnostic error likely to affect patient management – 3 marks. For each round, a perfect response would attract a score of 10 marks.

Thereafter a listing is prepared recording the total number of participants in the circulation, individual scores per case and total scores for the circulation (**EQAI01**).

This document and the marking exercise are then considered by the Management Committee and any amendments made. A provisional results sheet for the circulation is e-mailed to each participant prior to discussion and final agreement of the marking at the appropriate meeting of the Caledonian Branch of the Association of Clinical Pathologists.

A computer printout, the provisional results sheet, is presented which shows the marked response by each participant in the round by confidential code. This allows each participant in the Scheme to see their own performance in each case as compared to that of the other participants. The printout also allows participants to see the overall response to any particular case.

Thereafter the cases from the EQA circulation under consideration and results are presented usually within two to three weeks as part of the Participants Meeting, to which all participants are invited to attend. Following this meeting, any amendment to scoring of a case will be incorporated into the final

results sheet and a definitive results sheet is created as a permanent record of the circulation. The management team retain authority over any agreed changes to provisional marking.

3.7.4 Subcontracting

The evaluation of performance shall not be subcontracted by the scheme and shall remain the responsibility of the scheme management team. (See section Subcontracting Services and **EQAO06**).

3.8 Reports

3.8.1 Reports to participants

Reports to participants have a strong educational impact and should be clearly presented.

3.8.2 Presentation of results to participants

Two sets of results are sent to participants. Firstly, the provisional results are distributed after the Management Committee has met to discuss the results, but prior to the Participants Meeting open to all participants. The provisional results report sent to participants comprises:

- A clear identification of the Scheme, distribution date of results and Circulation number.
- A table of anonymised provisional results, in which participants can identify their own provisional score and compare it with others.
- Diagnoses as submitted by the relevant Management Committee members, both for the assessable and special educational slides.
- Library references for further reading (special educational slides only).
- A covering letter from the Scheme Administrator confirming the contents.

After the Participants Meeting, the final agreed results are sent to participants, and include:

- A clear identification of the Scheme, distribution date of results and Circulation number.
- A table of anonymised final results, in which participants can identify their own final score and compare it with others.
- Cumulative analyses of performance over time through their own cumulative total scores for previous circulations.
- Minutes of the Participants Meeting outlining the discussions of diagnoses and results.
- Certificates awarding points for Continuing Professional Development.
- A covering letter from the Scheme Administrator confirming the contents.

3.8.3 Interpretative Comments

Diagnoses, references and minutes of the Participants Meeting are generally all that is required to accompany the results sent to participants. However, any specific comments relating to a particular case and its diagnosis (for example a case that has been discounted subsequent to marking), would be clearly explained in the covering letter from the Scheme Administrator.

3.8.4 Validation of reports

Reports to participants are validated prior to dispatch. The Scheme Secretary and Data Administrator or Quality Manager check and approve all components prior to distribution by the Scheme Secretary.

3.8.5 Amended Reports

Where it is necessary to issue an amended report it will include:

a) A unique identifier by virtue of the following version number to that of the most recently dispatched version
b) A reference to the original and most recently dispatched version
c) A statement concerning the reason for amendment i.e. errors in data handling of the final report

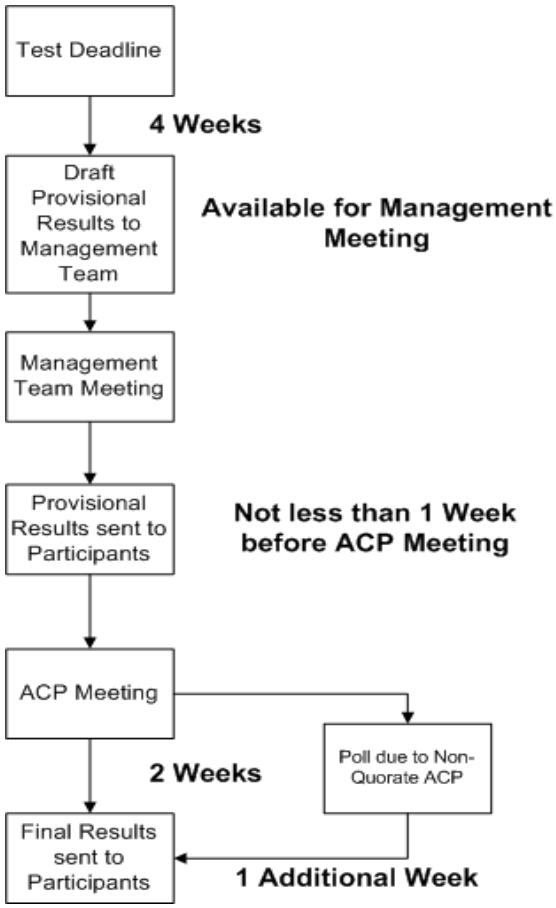
3.8.6 Use of Reports

Although participants may utilise their own cumulative score line from the final report at their discretion, the full final report cannot be used out with recognised professional and confidential circumstances e.g. in an appraisal situation.

Other annual reports compiled by the scheme for various professional bodies may be utilised with prior permission from the scheme executive team.

3.8.7 Timing of Reports

Reports are sent promptly in accordance with the following timetable in order to maximise benefits to participants:



The above programme enables participants to assess and prepare comments upon the provisional results prior to the ACP Meeting, and ensures that all results are received promptly whilst slides are still in the participating departments for reviewing by participants who so wish.

3.9 Communication with Participants

3.9.1 Participants' Manual

New participants are sent information which includes:

- Terms and conditions of participation, with a form to sign and return agreeing to abide by these
- A general description of the scheme (**EQAO01**)
- The practical details of Scheme design and procedures (**EQAO02 - 09**) are available on the scheme website at http://www.pathology.scot.nhs.uk/resources/pathologists-eqa/
- The website is administered by NSD and the scheme staff endeavor to keep the website informative and up to date for the benefit of the scheme participants. This is achieved by regular communication with the appropriate NSD support staff. In the event of a breakdown in this process support is provided by the NSD Senior Programme Manager.
- The mechanism of communication between EQA Scheme staff and participants (**EQAO01, 07**) are available on the scheme website
- The criteria for acceptable participation and performance (**EQAO01, 04, 05, 07**) are available on the scheme website
- The complaints procedure (**EQAQ02**) is available on the scheme website along with further information in 'The Complaints and Appeal' section of this manual.

3.9.2 Communication procedures and participant feedback

Two-way communication between the EQA Scheme organisers and the participants is an essential component of efficient and effective Schemes in laboratory medicine.

3.9.3 Procedures for technical advice to participants

If participants are unsure about an operational matter, they may contact the Scheme Secretary or Scheme Administrator who will provide guidance as necessary (**EQAO01, 06**).

3.9.4 Recording of communications

Communications to and from participants are recorded, logged and action taken documented (**EQAQ02**)

3.9.5 Complaints procedure

Where the communication may be construed as a complaint, the action taken to remedy the complaint is recorded and dated and appended to the original communication in the file. The complaint is also logged in Q-Pulse, the scheme's Quality management database.

If the Administrator 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:

- discussion at the Management Committee meeting
- production of a draft revision to the relevant SOP
- implementation, pending approval by the Management Committee
- discussion of any revision by the Management Committee
- Submission to RCPath if required, dependent on the magnitude of the change

The above procedures are clearly documented in the participants' manual, (**EQAO07, EQAQ02**)

3.9.6 Reports to participants

In addition to the regular written reports presenting results to participants (see the 'Reports' section of this manual), results are also presented and discussed at the Participants Meeting which always follows release of the Provisional results.

Participants are also informed of other non-routine matters in writing, such as a change in the Standard Operating Procedures when ratified by the college steering committee, or a change of Executive Team post holder.

3.10 Confidentiality

As detailed in **EQAO05**, the Scheme Secretary receives and keeps a record of all communication and responses from participants in a manner which ensures confidentiality.

The system guarantees that the Scheme Administrator remains unaware of individuals and/or their performance. This is achieved by a confidential numeric code system generated by the Data Manager. The Scheme Secretary has a list of EQA Scheme participants in paper form with a note of the numeric code for each participant. This paper record and the computer database represent the only link between the codes and the participants' name. The paper record is kept in a locked cabinet and is not made available to the Scheme Administrator, while the database is encrypted and password protected.

The Chairperson of the Management Committee communicates with participants when required on a personal basis by their code number only through the Scheme Secretary. Any confidential material from the Administrator is passed to the Scheme Secretary with only the relevant code number exposed, such that the communication is placed in an appropriately addressed envelope by the Scheme Secretary without the Secretary having to read the contents of the communication.

The link between participant names and code numbers may be divulged by the Scheme Secretary under only two circumstances:

1. In writing to a participant who requests a reminder of his/her code number. Code numbers must not be divulged by telephone.
2. In writing to the Chairperson of the Histopathology/Cytopathology National Quality Assurance Advisory Panel of the Joint Working Group on Quality Assurance, in order to investigate appropriately a case of persistent substandard performance in the EQA Scheme under the terms of SOP **EQAO07**.

No EQA result may be divulged to any other authority without the prior knowledge of the participant.

4 MANAGEMENT REQUIREMENTS

4.1 Organization

The Scotland and Northern Ireland EQA Scheme in General Histopathology is based in Dundee within Ninewells Hospital Pathology Department within Specialist Services of the Access and Assurance Care Division of NHS Tayside, which is the legally identifiable entity.

This scheme takes full responsibility to carry out its proficiency testing operations in such a way as to meet the requirements of ISO/IEC 17043:2010(E) and to satisfy the needs of its participants and regulatory authorities.

The EQA Scheme shall be directed by an Organiser with appropriate scientific training, authority, resource and experience in the field of operation.

It is recognised within our scheme that the Chairperson and Administrator will be fully qualified consultant histopathologists operating in a fully accredited department.

Responsibilities can be summarised as follows:

Officer	1st level line management: Responsible to:	2nd level line management: Responsible to:	Main Responsibilities
Dr Geraldine O'Dowd Chairperson	NHS Tayside	NSD	• Chair meetings • Performance correspondence with participants • Promotion of Scheme
Dr Neil Kernohan Administrator	Dr Geraldine O'Dowd	NHS Tayside	• Management and administration of scheme • Promotion of scheme
Lianne Duffy Quality Manager	Dr Neil Kernohan	NHS Tayside	• Ensuring compliance with ISO 17043 • Maintenance of quality management system • Plan and record all audits • Process complaints and non-compliances • Document management • Maintenance of confidentiality
Dr Stuart Thomas Data Manager	Dr Neil Kernohan	NHS Tayside	• Development and maintenance of data bases • Data analysis and maintenance of confidentiality • Purchase and maintenance of IT equipment
Linda McDonald Scheme Secretary	Dr Neil Kernohan	NHS Tayside	• Organisation of slide circulation • Typing of all records • Arrange meetings • Communication with participants • Maintenance of confidentiality

4.1.1 Conflicts of Interest

Conflicts of interest can occur within the personnel of the scheme and it is important that these are recognised and handled appropriately with proper procedures put in place.

Any possible conflicts of interest will be raised with the executive committee, who will discuss and put in place any suitable procedures required.
Recognised examples within the scheme include:

1) The Quality Manager carrying out all audits of the schemes' quality management system.

Solution: An appropriately qualified Quality Manager from the host or other NHS Tayside department carrying out some of the scheme audits. This task can then be reciprocated by the scheme Quality Manager carrying out audits for other departments.

2) The Chairperson and Administrator also take part in the scheme as participants, giving arise to a possibility of influencing marking.

Solution: The Chairperson and Administrator submit diagnoses for all 20 assessment cases prior to case selection and these diagnoses are submitted for marking, with all diagnoses results discussed by the full management team.

4.2 Management System

4.2.1 Quality Manual

This Quality Manual describes the Quality Management System of the Scotland and Northern Ireland EQA Scheme in General Histopathology. Throughout the text there are references to scheme procedures (in bold) written in fulfillment of ISO/IEC 17043:2010.

This Quality Manual fulfills two functions. It describes the Quality Management System for the benefit of the EQA Scheme Provider's own management and staff, and it provides information for users and for inspection/accreditation bodies.

This Quality Manual can be regarded as the index volume to separate volumes of Standard Operating Procedures that encompass Management, Operational, Information Technology and Quality procedures. The sections of the Quality Manual are arranged so that they equate with the UKAS standard ISO/IEC 17043:2010 (see table below). Under the title of each standard there is a brief description of the way in which the Scotland and Northern Ireland EQA Scheme in General Histopathology seeks to comply with the particular area of the standard and references are given to appropriate procedures.

4.2.2 Quality Policy

The Quality Policy of the Scotland and Northern Ireland EQA Scheme in General Histopathology is given below and published as a separate controlled document to be displayed within the scheme office.

The scheme office is sited within the Pathology Department of the Single Delivery Unit of NHS Tayside. The scheme is committed to providing a service of the highest quality and shall continue to be aware of and take into consideration the needs and requirements of all participants and customers of the scheme.

The Scotland and Northern Ireland General Histopathology EQA Scheme will comply with standards set by UKAS in the International Standard ISO /IEC 17043:2010 and is committed to continually improving the effectiveness of the management system by:

- Operating a quality management system to integrate the organisation, procedures, processes and resources, to achieve the highest level of quality within the scheme.
- Setting quality objectives and plans in order to implement this quality policy
- Ensuring that all personnel are familiar with this quality policy along with all other quality documentation and implement all scheme policies and procedures to ensure user satisfaction
- Committing to the health, safety and welfare of all staff. Visitors to the scheme office will be treated with due respect and consideration will be given to their safety whilst on site
- Committing to compliance with all relevant environmental legislation
- Upholding professional values and being committed to good professional practice and conduct.
- Having in place staff recruitment, training, development and retention such as to ensure an appropriate and effective service to its users
- Having the proper procurement and maintenance of such equipment and resources as are needed for the provision of the EQA Service
- Having the appropriate collection, transport and handling of all assessment and educational slides
- Ensuring the reporting of results of slide circulations in a timely, confidential and accurate manner
- Carrying out internal audit in order to produce a continual quality improvement
- The assessment of user satisfaction

Quality Policy authorised by:

Position: **Scheme Chairperson**_____

Signature: 

4.3 Document Control

This area of the standard is fulfilled by procedure **EQAM01**, which states that the permanent members of the Management Committee (the Executive Team) are responsible for requesting, and writing, all documentation.

All documents will be administered within Q-Pulse, a Quality Management administration programme available within Ninewells Hospital. Preparation of draft documents and authorisation will all be carried out within Q-Pulse.

After preparation and before issue the documents will be verified for practical use by the scheme quality manager, who will also edit for clarity, accuracy, suitability and proper structure before authorisation by relevant members of the Executive Team.

4.4 Review of Requests, Tenders and Contracts

4.4.1 Modifications to the Scheme

The EQA Executive Committee is responsible for approval of any changes in EQA scheme design, including the introduction of new procedures and the cessation of existing procedures, along with the assessment of capability and resources for any proposed new work. These changes are proposed by clinical members of the Management Committee, or by the Executive Team as a result of:

- Management Review
- Internal or external audit
- Executive Team Meetings
- User surveys and participant requests
- Requests or suggestions from external bodies, such as UKAS, NQAAP and NSD.

4.5 Subcontracting Services

If any element of the EQA Scheme (for example, manufacture of samples, packaging and distribution, statistical analysis of results) is contracted out, it is important to ensure that it is controlled so as not to compromise the effectiveness of the service.

No elements of the EQA Scheme are currently contracted out, apart from the provision of test slides. All contributing departments must be accredited, as described in **EQAO03**.

Although unlikely, should any other aspect of the EQA scheme need to be subcontracted, it will be placed with a competent subcontractor and the EQA scheme will be responsible for this work.

The evaluation of performance shall not be subcontracted by the scheme and the final results will remain the responsibility of the scheme management team, as detailed in **EQAO06**.

4.6 Purchasing Services and Supplies

4.6.1 Procurement and Management of Equipment and Supplies

The proper procurement and management of equipment and supplies ensures that the scheme can fulfil the needs and requirements of users.

4.6.2 Responsibility

The Scheme Executive team ensures that the equipment and supplies required is sufficient and appropriate to provide the service.

4.6.3 Procedure

For generalist equipment such as the Scheme's computer or slide transportation boxes, the NHS Tayside procedure for the procurement of equipment must be followed: "NHS Tayside Standing Orders Section B: Competitive Tendering". This includes selection and acceptance of quotations and tenders.

Documentation relating to other aspects of equipment procurement is found in Pathology Department procedure **MAA015,** along with **EQAM 08** and covers the following areas: -

- assessment and justification of need,
- selection and acceptance
- training, (if provided by manufacturers, is part of the specification)
- maintenance, service and repair
- planned replacement and disposal
- record of equipment failure and subsequent corrective action

All purchasing of equipment and supplies by the scheme will follow NHS Tayside procedures and be obtained from sources approved by NHS Tayside.

4.6.4 Inventory

The scheme keeps a limited inventory of scheme equipment and approved sources of suppliers within **EQA Form 12,** controlled within Q-Pulse and includes:

- name of manufacturer
- serial number
- record of contracted maintenance
- Record of equipment downtime

Records of equipment electrical safety checks are held by Medical Physics at Ninewells Hospital.

4.7 Service to the Participant and Customer

4.7.1 Assessment of participant satisfaction

The purpose of assessing participant satisfaction is to establish that the service provided meets the needs of participants.

4.7.2 Procedures

The Executive Team established, in 2003, a simple questionnaire based survey to assess user satisfaction. This survey will be carried out at least every 3 years and all processes and procedures reviewed accordingly.

The scheme secretary is the point of contact for all queries. All feedback from participants is openly encouraged. The scheme's procedures for appraisal and improvement of the service provided are detailed in **EQAQ02**.

Participants are enabled to comment upon the clinical relevance of the EQA Scheme design and the reliability of interpretative reports via the Caledonian Branch ACP Meeting, held twice per year after release of the Provisional results.

Performance targets in relation to user satisfaction are assessed during the Management Review.

4.8 Complaints and Appeals

The scheme secretary is the point of contact for all complaints and appeals.

4.8.1 Complaints

EQAQ02 defines procedures for monitoring, reviewing and acting upon complaints data.

All complaints will be logged. The Quality Manager must be informed of any complaints and they will be logged within the CA/PA module within Q-pulse. Any outcomes will be acted upon and corrective and preventive actions recorded. A written response must be sent and recorded, along with any action taken to remedy the complaint.
If the Quality Manager 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:

1. Discussion at the Executive Team Committee meeting
2. Production of a draft revision to the relevant SOP
3. Implementation, following approval by the Executive Committee
4. Notification to NSD of any major changes in the running of the scheme.

4.8.2 Appeals

Any appeals against the final result issued should be made in writing and sent to the scheme secretary within two weeks of the results being issued. The appeal will be discussed by the executive committee and a response sent to the participant.

4.9 Control of Nonconforming Work

Should any aspect of the schemes activities be found not to conform to its own procedures or the agreed requirements of its participants, the details shall be recorded as a Critical Incident, as described in **EQAQ02,** and corrective and preventive actions recorded and actioned, along with timescales.

An evaluation of the significance of the nonconforming work shall be made by the scheme Quality Manager, along with carrying out a root cause analysis and the necessary action will be decided by consensus between available Executive Team members.

Necessary actions may include:

- Recall of results
- Recall of test slide/slides
- Re-issue of poor performance notifications.

All relevant participants will be notified as soon as possible should any necessary actions be required.

4.10 Improvement

Continual quality improvement is an essential part of maintaining and improving EQA Schemes in laboratory medicine.

4.10.1 Processes for improvement

Through the procedures described in **EQAO08, EQAQ02 and EQAQ03**, along with those included in the Management Review, the scheme incorporates continual quality improvement, including corrective action, preventative action and improvement processes. The Quality manager carries out vertical, horizontal and examination audits.

During audit, an auditor may find issues which do not result in a non-compliance, but where scheme practice or governance could be improved. In these circumstances a quality improvement suggestion is recorded within Q-Pulse.

The Quality Manager assists the Executive Team and the Management Committee as a whole to ensure that optimum improvements are achieved.

4.11 Corrective Actions

EQAQ02 and EQAQ03 define actions to be taken for identification and elimination of the causes of non-conformities.

The Quality Manager shall be responsible for implementing corrective actions when nonconforming work or departures from policies have been identified and these shall be recorded within Q-Pulse.

If a non-conformance is raised during audit, the auditor records the incident against the audit, within Q-Pulse. Corrective actions and completion dates are also recorded.

The auditee or the responsible executive team member records remedial action or reasons for taking no action. A completion date is recorded.

Details of any further process investigations and actions, as well as a completion date and signature are also recorded.

When serious issues have been identified, a further audit of all corrective action is carried out. The results are recorded, dated and signed off.

These actions are evaluated as a component of the Management Review and are discussed and minuted regularly at Executive Team meetings.

4.12 Preventive Actions

4.12.1 Preventative action for non-conformities

EQAQ02 and **03** define preventative actions to be taken to reduce non-conformities. The procedures include:

- investigation of the causes of potential nonconformities and recording of results
- determination of and responsibility for preventive action.
- implementation of preventive action required and an agreed timescale
- ensuring that the preventive action taken is effective, recorded and submitted for management review

EQAO04 and **EQAO07** also contain measures to prevent nonconformities, for example double checking of input of scores into the computer record system.

These actions are evaluated as a component of the Management Review.

4.13 Control of Records

This standard is fulfilled by procedure **EQAM02**, which defines a procedure for the control of all Technical and Quality records, including the Quality Manual

4.13.1 Responsibility

The Scheme Secretary has primary responsibility for ensuring that all technical records and clinical material (slides) are stored securely. The Scheme Secretary is the point of contact for members of the Executive Committee to access the documents/slides. Authorisation for viewing of anonymised records by persons other than Management Committee members must be obtained from the Scheme Administrator.

The Quality Manager has primary responsibility for all quality related documents and the procedures and template letters are to be held as follows:

- Electronic copies on Q-Pulse
- Paper master copy stored by Quality Manager
- Previous archived versions are stored on Q-Pulse

Procedures are also currently available on EQA Web page at: **http://www.pathology.scot.nhs.uk/resources/pathologists-eqa/** for reference by participants.

All other quality related documents are held securely by the quality manager.

All data entries, changes and checks of document hard copies shall be initialed and dated at the time they are made, by the staff member concerned.

4.14 Internal Audits

4.14.1 Internal audit of quality management system

Internal audit provides evidence to demonstrate that the quality management system has been effectively established, implemented and maintained.

4.14.2 Establishment of internal audit

The internal audit procedure has been devised by the Quality Manager, for approval by the Management Team.

4.14.3 Audit processes

The process for internal audit is defined in **EQAQ03**. It is scheduled to be carried out on an annual basis, conducted against criteria agreed by the Executive Team for approval by the Management Committee, and is carried out by the Quality Manager, who is trained in internal audit.

4.14.4 Record of the audit

All audits are recorded in Q-Pulse and include:

- The activity areas and items covered
- Any non-conformities or deficiencies found
- The recommendations and timescale for remedial, corrective and preventative action

4.14.5 Evaluation and review

The Management review process includes evaluation of the results of internal audit. The decisions taken are documented, monitored, reviewed and acted upon. The procedure is defined in EQAQ 02 and any major changes to the scheme communicated to participants.

4.14.6 Internal audit of EQA Scheme operation

Internal audit of the operation of the EQA Scheme is required to ensure that it is being conducted according to agreed procedures.

4.14.7 Responsibility

The Quality Manager, who is trained in internal audit, carries out an annual internal audit of the operation of the EQA Scheme.

4.14.8 Audit Process

The process is planned and scheduled, once per year. It is conducted against criteria agreed by the Management Committee and defined in **EQAQ03**.

All components are recorded within Q-Pulse.

It comprises vertical and examination audit techniques.

4.14.9 Audit components

As with the internal audit of the quality management system, the EQA operation internal audit record includes:

- The activities, areas and items covered.
- Any non-conformities or deficiencies found.
- The recommendations and timescale for remedial, corrective and preventative actions.

4.14.10 Evaluation and review

The Management review (A11) process includes evaluation of the results of internal audit. The decisions taken are documented, monitored, reviewed and acted upon. The procedure is defined in **EQAQ03** and any major changes to the scheme communicated to participants.

4.15 Management Reviews

The EQA Scheme management team conduct an annual review, as described in **EQAO08** that considers the following items of information

a) Suitability of policies and procedures
b) Reports from managerial and supervisory personnel
c) Outcomes of internal audit of quality management system and internal audit of EQA Scheme operation. These are described in procedure **EQAQ03**
d) Status of preventive, corrective and improvement actions. These are described in procedures **EQAQ02** and **EQAQ03**
e) Reports of assessments by external bodies
f) Changes in the volume and type of work
g) Customer, advisory group or participant feedback
h) Assessment of participant satisfaction, appeals and complaints. This standard is fulfilled by procedure **EQAQ02**
i) Recommendations for improvement
j) Major changes in organisation and management, resource (including staffing) or process.

Records are kept and key objectives for subsequent years defined and plans formulated for their implementation. A copy of the Management Review will be sent to UKAS annually, along with NSD and NQAAP.