Scotland and Northern Ireland EQA Scheme in General Histopathology

EQAQ02

QUALITY IMPROVEMENT

ISO 17043:2010 ref	5.7 to 5.12
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Review and Amendment History			
Date Reviewed / Amended	**Version Replaces**	**Pages Changed**	**Details of review/Amendment**
Feb 2021	5.0	2 Pages (Front, 2)	Updated location of copies (front pg), added table of contents (Pg2)

Table of Contents

1 PURPOSE

Continual quality improvement is an essential part of maintaining and improving the objectives and aspirations of the scheme. This procedure will cover processes for continual quality improvement and will include corrective action, preventive action and improvement processes.

This procedure **does not** replace logging any Health and Safety issues occurring within the host building on the NHST DATIX system.

2 PROCEDURES

2.1 Non Conformance Logging

2.1.1 Minor Errors

Every time a minor error occurs which may have resulted in an incorrect result or work of an inferior quality being issued, an entry must be recorded within the Q-pulse CA/PA module, as described in section 2.3 'Entering Incident on Q-Pulse' below. These will be audited regularly by the Quality Manager and any areas requiring action will be reported to the Executive Team.

2.1.2 Critical Incidents

If a critical incident is deemed to have taken place then the Quality Manager must be informed and the incident must be raised within the Q-pulse CA/PA module, as described in the section 2.3 'Entering Incident on Q-Pulse' below. A critical incident is one that has resulted in an incorrect result being issued or any other error being issued by the scheme which will have, or has had, an adverse effect on a participant. All critical incidents will be discussed by the executive team and a Root Cause Analysis carried out and recorded, with appropriate corrective measures put in place.

2.1.3 Verbal Complaints

Logging of verbal external complaints received will be recorded by the Quality Manager within the Q-pulse CA/PA module, as described in the section 2.3 'Entering Incident on Q-Pulse' below. These will be discussed by the executive team and appropriately responded to.

2.1.4 Written Complaints

All written complaints will be logged. The Quality Manager must be informed of any written complaints and they will also be recorded within the CA/PA module within Q-pulse, as described in section 2.3 'Entering Incident on Q-Pulse' below. Any outcomes will be acted upon and procedures amended accordingly. A written response must be sent and recorded, along with any corrective actions taken to remedy the complaint.

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:

1. Discussion at the Executive Team Committee meeting
2. Production of a draft revision to the relevant SOP
3. Implementation, pending approval by the Steering Committee
4. Discussion of any revision by the Steering Committee

2.1.5 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. They will also be recorded within the CA/PA module within Q-pulse, as described in section 2.3 'Entering Incident on Q-Pulse' below.

2.2 Communications

All written communications from participants to the Administrator or the Secretary are stored in a file for a minimum of five years. Where a telephone or verbal communication is made, the Administrator or Secretary receiving the communication makes a written note summarising the communication and that is dated and stored in the file.

Where the communication may be construed as a complaint, the action taken to remedy the complaint is recorded and dated and clipped to the original communication in the file.

2.3 Entering Incident on Q-pulse

- Open the CA/PA module within Q-pulse.
- Using the drop down black arrow beside the top left icon on the tool bar "Create a new Non-Conformance) and select "from wizard" and then "EQA scheme"
- Within the "Source" field, select the drop down from "Pathology", then the drop down from "EQA" and select the type i.e. Complaint, Critical Incident, Minor Error etc.
- Work through the wizard, entering as much information as possible, using the drop down options where available and applicable.
- Inform the QM that an incident has been raised.
- The QM will set realistic target dates for immediate and corrective actions.
- Immediate actions should be within one week and corrective actions may be discussed at the next Executive team meeting.
- All minor errors, critical incidents and complaints will be reviewed and minuted at Executive Team meetings

2.4 Control of Non-Conforming Work

By definition "Non-Conformance" simply means, "the thing that actually happened, did not conform to what we had intended". It is important to capture information around the volume and type of instances when things didn't go as they were intended.

When procedures and outcomes are not as intended it may lead to:

- Adverse or less favourable outcomes for the scheme, staff, participants or organisation.
- Neutral outcomes but a deviation from practice that may lead to uncertainty and lack of standardisation of approach.
- The conclusion that what was intended is no longer suitable and needs revised.

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 section 2.1.2 above and immediate and corrective actions recorded and actioned, along with timescales.

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

Identification of non-conforming work can arise from various sources within the scheme, including:

- Participant complaints
- Management reviews
- Audits
- Test slide preparation and dispatch
- Data analysis
- Instructions to participants
- Sending of results
- Slide handling and storage

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.

Responsibility for the resumption of work following the completion of any corrective and preventive actions will be taken by available Executive Team members.

Areas that must be considered within any non-conformance include:

Remedial Action: "Remedial Action" is a term referring to actions taken to counteract deficiencies or undesirable characteristics in products and processes. These must be completed on Q-Pulse against the non-conformance and describes the actions taken immediately upon discovery of the non-conformance.

Root Cause Analysis or Investigation Summary: RCA generally serves as input to a remediation process whereby corrective actions are taken to prevent the fault/problem from reoccurring. It helps to avoid the tendency to single out one factor to arrive at the most expedient (but generally incomplete) resolution. It also helps to avoid treating symptoms rather than true, underlying problems that contribute to a problem or event.

The primary goals of using RCA is to analyse problems or events to identify:

- What happened
- How it happened
- Why it happened…so that
- Actions for preventing reoccurrence are developed

Carrying out an RCA will help:

- Identify barriers and the causes of problems, so that permanent solutions can be found.
- Develop a logical approach to problem-solving, using data that already exists.
- Identify current and future needs for organisational improvement.

These must also be completed on Q-Pulse against the recorded non-conformance.

Corrective Actions: Corrective action is action taken to eliminate the cause of a detected non conformity or other undesirable situation and there can be more than one cause for a non-conformity. Corrective actions are taken to prevent recurrence.

The Quality Manager shall be responsible for implementing corrective actions when nonconforming work or departures from policies have been identified and these shall also be recorded within Q-Pulse. Regular reviews, annually as a minimum, will be carried out to ascertain the effectiveness of all corrective actions put in place. These actions are also evaluated as a component of the Management Review and are discussed and minuted regularly at Executive Team meetings.

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

Preventive Actions: Preventive action is action taken to eliminate the cause of a potential non conformity and prevent occurrence. It is a pro-active process for identifying opportunities for improvement rather than a reaction to the identification of problems or complaints. Areas for improvement and potential sources of nonconforming work shall also be recorded and the procedures shall 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.

All preventive actions are recorded in Q-Pulse using the process outlined below:

- Open the CA/PA module within Q-pulse.
- Using the drop down black arrow beside the top left icon on the tool bar "Create a new Non-Conformance) and select "from template" and then "EQA Preventive Action"
- Within the "Source" field, select the drop down from "Pathology", then the drop down from "EQA" and select the type "Preventive Action".
- Work through the wizard, entering as much information as possible, using the drop down options where available and applicable.
- The QM will set realistic target dates for the preventive actions to be put in place. Preventive actions will be discussed at the next Executive team meeting.

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

3 PARTICIPANT MEETINGS

Meetings with participants provide valuable feedback. After the release of each set of provisional results, scheme participants have the opportunity to attend a meeting of the Caledonian Branch of the Association of Clinical Pathologists. The members of the Management Committee who provided slides for the current circulation are present at the meeting along with the scheme chairman. The two committee members who have provided the special educational slides give presentations on the relevant cases. The meetings give participants the opportunity to discuss matters relating to the provisional results and the relevant cases, as well as general matters relating to the scheme.

The discussions may lead to alterations to the provisional results, so that the final results are only released after these meetings.

4 USER QUESTIONNAIRE

The requirements and views of the participants of the scheme are also gathered via a Participant Questionnaire Survey, which will be repeated at least every 3 years. A summary report of this is to be presented to the Management Committee and to participants, with opportunity for comment. The Management Committee will consider any appropriate revisions required to scheme operation as a result of these surveys, with amendments as necessary to the Standard Operating Procedures and the Quality Manual incorporated into the annual Management review process.