

Job Aid 3: QC NCE Examinations 911v2

Identification and Control of Quality Control (QC) Nonconformities (ISO 15189 Clauses 4.9 and 5.6.2.3)

- Internal QC events
- Proficiency Testing (PT) reports
- Interlaboratory Comparison reports
- Examination Quality Indicator (QI) exceeding threshold
- Calibration failures

QC failure event has occurred.

QC failure event is identified.

- Management must develop and implement the QC protocols (criteria) for each test which alerts the analyst to a significant change in the analytical system.
- It may take several analytical runs or even days to detect an internal QC failure.

Examinations are halted and reports withheld as necessary.

- Management must define when the delay notification procedure goes into effect.
- Patient results which may be affected (determining extent) include all samples analyzed since the last successful QC event, (ISO 15189 Clause 5.6.2.3)

Medical significance of the NCE is considered.

Some aspects to consider include:

- Is it a life threatening analyte (i.e. included on your critical call list)?
- Are results (and cut-off values, where applicable) too high, too low, or imprecise?
- What is the intended use of the test?

Wrong results released?

YES

Results already released are recalled.

Ensure that, where the amended procedure addresses recalls, it includes instructions on notifying the provider or authorized individual responsible for using the results, and documenting this notification.

NO

Troubleshooting Process

Determining the cause(s) of the problem and implementing a solution (corrective action)

If results were initially too high or too low, then select several sample concentrations for pre and post testing that targets the same area.

NO

Alert section supervisor or call hotline for assistance.

Is QC acceptable ?

Determining the effectiveness of the corrective action taken

YES

Authorization is given to resume when quality specifications are within tolerance limits.

- Once able to resume testing, try to address *urgent* and possible criticals first.
- If the delay has been extended, then consider how the test will be used. In some cases, the backlog may be better handled by analyzing the most recent samples first.

Results are reported, and previous patient sample comparisons are checked and recorded.

The amended procedure needs to address 2 scenarios types:

- examination results that are discovered to be incorrect while the samples are still available for retesting;
- examination results that are discovered to have been incorrect but are unable to be retested (e.g. sample no longer stable or discarded, or a long-term QC failure event has occurred).

Necessary reports are amended.

Log an occurrence report if erroneous results have been released. The investigation MUST include why QC processes failed to alert the laboratory when method performance no longer met quality specifications.

Description of event and action taken are documented.

Consider having a *corrective action* log for each test or workstation for documentation purposes. This quality record should be reviewed at regular specified intervals looking for trends.

QC failure event is closed.