RANDOX
QUALITY CONTROL

Improving Laboratory Performance Through Quality Control

Five simple steps for QC success

How Often is Right for QC?

Ask the Right Questions to get the Right Answers

Complete **QC** solutions for results you can **trust**

How Often is Right for QC?

It is widely accepted that laboratories should perform QC at least every day of patient testing. However, is this adequate for every assay and for every laboratory? Is running QC once per day really sufficient? What is the **"right"** frequency for running QC samples in your laboratory?

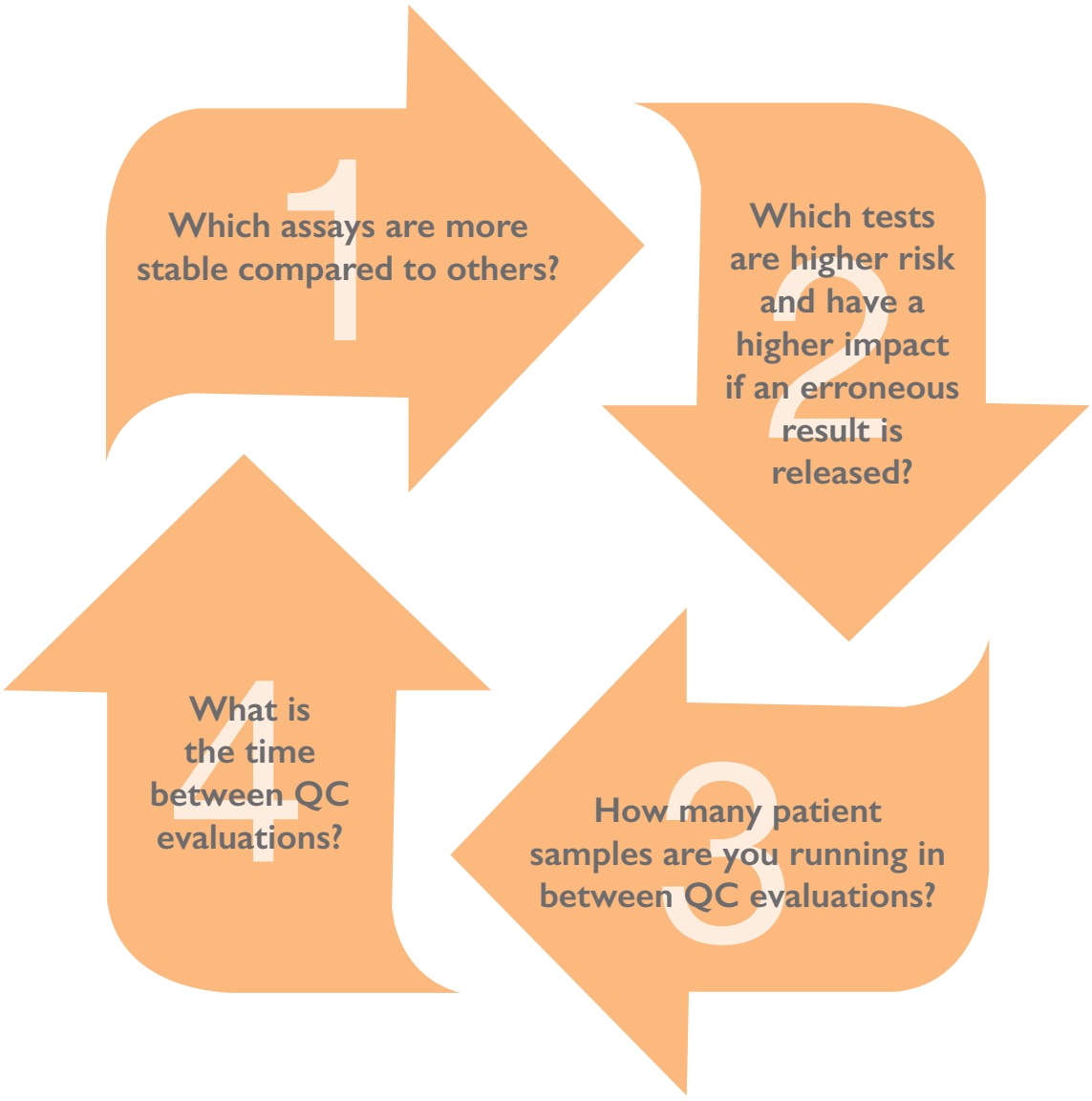
ISO 15189 regulations don't state a recommended QC frequency but they do recommend that

"Quality Control materials shall be periodically examined with a frequency that is based on the stability of the procedure and the risk of harm to the patient from an erroneous result".

ISO 15189 understands that differing tests and situations will require differing QC frequencies.

So how do you use this advice to work out the correct QC frequency for each assay in your lab?

There are various factors in line with ISO regulations that you need to consider when deciding an appropriate QC frequency. Deciding an appropriate QC frequency, starts with asking the right questions.



It is of great importance that laboratories ask all of these questions in order to determine the "right" QC frequency. If you ask the 'right' questions, you'll get the 'right' answers.

1. Which assays are more stable compared to others?

Some assays naturally perform better than others, giving consistently better results and rarely producing any errors. On the other hand, some assays perform inconsistently, having a higher rate of error and much lower stability.

It's important that laboratories can recognise which assays are more stable and consistent in comparison to others and ensure that they are running QC at an appropriate frequency, in order to detect any clinically significant errors.

By utilising an EQA scheme and/or peer group reporting programme, method validation and peer performance comparison can be monitored, helping laboratories to assess their precision over time and easily identify which tests generally perform better.

Identify any unstable assays and increase QC frequency for those assays.

2. Which tests are higher risk and have a higher impact if an erroneous result is released?

It's important that you run QC more frequently for higher risk tests. With higher risk tests there is a greater possibility of harm to the patient, therefore it's of utmost importance that the results released are both accurate and reliable.

Any tests that have the following characteristics should be considered high risk and QC should be run more frequently in these instances.

- **A test where there could be a detrimental consequence, should the wrong test results be released**
- **A test that supports the clinician's decision in isolation**
- **A test that is acted upon immediately**
- **A test that is performed on a specimen that is difficult/painful to collect**

3. How many patient samples are you running in between QC evaluations?

This is an important factor that must be taken into consideration when deciding QC frequency. Imagine there are two labs "Lab A" and "Lab B", both of which perform QC every morning. That's sufficient, correct?

Now consider that 'Lab A' tests 10 patient samples a day, whereas Lab B tests 1000 patient samples a day. Is performing QC once per day still sufficient for each lab? Say an error occurred in the test system after 50% of the patient samples had been tested, both labs would not recognise that they had a QC failure until the next day. Arguably, this could be problematic for both labs as erroneous patient results may have been released.

In both cases, they will have to re-evaluate the patient samples from the last successful quality control event as recommended by ISO 15189.

Potentially Lab B will have to repeat 1000 patient samples, costing a significant wastage of both time and resources. Ideally patient samples should be run in batches, starting and ending with a QC evaluation, perhaps running QC every 50 or 100 patient samples.

This will save time, save money and most importantly this will reduce risk of harm to the patient.

4. What is the time between QC evaluations?

Let's consider another scenario, both Lab A and Lab B now decide to change their QC strategy. Instead of running QC once per day, they now decide to run it every 100 patient samples. Great news, correct? This perhaps is good news for Lab B, as they will now be running QC more frequently, reducing risk for their patients. However, this is not so good for Lab A. Let's say that an error occurs after 50 patient samples have been run. For Lab B, they will detect the problem straight away on day 1 and will be able to investigate the problem preventing the release of erroneous patient results.

For Lab A, the error will have occurred on day 5 of their patient testing, but the problem would not be recognised until day 10. This could spell disaster for any laboratory, with the release of potentially erroneous results causing misdiagnosis, incurring cost and resulting in a negative impact on patient care.

Therefore, it's of utmost importance that you consider the time between QC evaluations in addition to the number of patient samples being tested. Keep the time between QC evaluations shorter than the time needed to undertake any corrective action in the case of an erroneous result. This is a good rule of thumb to ensure you select an appropriate QC frequency.

It's good to take a holistic approach and take all factors into consideration.

Conclusion

Unfortunately there is no straightforward answer to how frequently you should run QC. However, if you ask the right questions, you'll reach the right answer. Make sure you are running QC more frequently for high risk and unstable tests, that you start and end patient testing with a QC evaluation and you make the time between QC evaluations shorter than the time needed to take corrective action in the case of an erroneous result.

Finally QC samples should also be tested before and after any event that has the potential to adversely affect the testing process e.g. change of reagent batch, instrument maintenance and calibration. Testing prior to the event provides confidence that patient results since the last successful QC check are reliable. Testing QC samples immediately after the event ensures the test system is in control prior to running more patient samples. In the case of an unplanned event QC testing should still be performed immediately after the event to assure the testing process is operating correctly before continuing with patient testing.

Acusera Advisor*

Designed for use with the Acusera range of third party controls, our Acusera 24•7 software will help your lab monitor and interpret your QC data. Acusera Advisor is a tool that automatically recommends QC multi-rules and optimal frequency for each individual test used in your lab.

Employing Acusera Advisor in your lab will reduce false rejections and unnecessary troubleshooting, therefore saving time and money on expensive repeat tests.

Recommendations are based on normalised OPSpec charts. Once performance limits have been defined, the software will determine the %CV and %Bias. These are then used to calculate the normalised operating point. A normalised OPSpec chart is then used to select the appropriate QC strategy.

*** not available in USA**

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