RANDOX

# EDUCATIONAL GUIDE

## ISO 15189:2012 Accreditation Guide

QUALITY CONTROL

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Approximately 70% of clinical decisions are based on laboratory test results. Poor laboratory quality can result in unreliable test results ultimately leading to misdiagnosis, inappropriate treatment and may even impact the overall quality of life for the patient. The importance of quality medical services is recognised globally with several bodies existing internationally including ISO (International Organisation for Standardisation) who have developed a set of guidelines and quality systems to ensure reliable test results - ISO 15189:2012. This guide will outline what you need to consider and implement with regards to quality control to gain and maintain ISO 15189:2012 Accreditation.

## Accreditation vs Certification

Accreditation is a *"procedure by which an authoritative body gives formal recognition that a body or person is competent to carry out specific tasks".*

Certification is a *"procedure by which a third party gives written assurance that a product, process or service conforms to specified requirements".*

Source: ISO/IEC Guide 2

It is important to differentiate between accreditation and certification to ensure you have the industry required standard for medical testing. ISO 15189 is an accreditation standard that is authorised by a third party organisation, who is independent of the laboratory.

## About ISO 15189:2012

ISO 15189:2012 was designed to outline the *"requirements for competence and quality that are particular to medical laboratories"*. Laboratory competence and quality are critical in patient diagnosis and care to ensure they meet the need of the clinicians & patients. Gaining accreditation to ISO 15189:2012 will assure clinicians employing your services that they will be benefitting from accurate results which have been measured against a consistent standard. You could benefit too from cost savings and enhanced end-user satisfaction.

## Gaining Accreditation

ISO 15189:2012 divides the quality requirements of the laboratory into two distinct areas; Internal Quality Control (IQC) and External Quality Assessment (EQA). By combining both of these you can comprehensively review and monitor the overall performance of your laboratory, including personnel, equipment and procedures. In order to gain accreditation you need to consider the following;

1. First vs. Third Party Controls
2. Commutable Controls
3. Clinically Relevant Levels
4. Peer Group Reporting
5. EQA

## 1. First vs. Third Party Controls

Quality Control products that have been developed and manufactured by the instrument/reagent manufacturer are considered First Party Controls and as such they are referred to as instrument dependent controls. These controls have generally been optimised for use with the manufacturers test system. Whilst this may appear to be beneficial using such First Party Controls will often mask a multitude of weaknesses and consequently are believed to lead to perceived accuracy and a biased assessment of performance. Therefore we can conclude that employing First Party Controls will not detect errors in the laboratory but simply mask them.

On the other hand Third Party Controls are manufactured independently of any specific test or system. Manufacturers of Third Party Controls will often assign values based on data collected from thousands of independent laboratories, thus ensuring the data available covers a range of methods and analysers. Due to their inherent independent nature & objectively assigned values you can be assured that Third Party Controls will provide unbiased error detection across multiple platforms and methods.

Did you know?

**ISO 15189:2012 recommends the use of** *"third party control materials, either instead of, or in addition to, any control materials supplied by the reagent or instrument manufacturer"*

## 1. Commutable Controls

It is essential to ensure the quality control material you select is fit for purpose. The ideal quality control should mimic the patient sample and behave in the same way to ensure accurate test system performance. When running immunoassay based methods, the quality controls used should be manufactured using 100% human material. Controls manufactured from 100% human material will behave in the same manner as a patient sample when tested and can therefore be described as commutable. However when employing controls which contain non-human components you are likely to experience shifts in QC values when reagent batches are changed. These shifts are not reflected in the behaviour of patient samples and as such we can conclude that they are the result of the non-human components present in the controls. This is supported by Miller, et al (2006) who states that using *"enzymes of non-human origin"* in quality controls such as immunoassay, haematology or cardiac *"can produce a different measurement signal than expected for native forms of the analyte".*

Did you know?

**ISO 15189:2012 recommends the use of** *"quality control materials that react to the examining system in a manner as close as possible to the patient sample"*

## 3. Clinically Relevant Levels

In addition to features such as third party and commutability, you should also consider whether the quality controls you are using contain analytes at clinically relevant levels. Karkalousos and Evangelopoulos (2011) define clinically relevant levels as levels which are used to *"check the performance of laboratory methods across the measuring range"*. For example, when measuring Troponin T the cut off value is 14 ng/l. Any patients who present to the hospital with a concentration higher than 14 ng/l in their blood is said to have had a cardiac event. Test results lower than 14 ng/l would either indicate that the patient is healthy or it is too early to tell if a cardiac event has occurred. As such it is imperative that analysers can accurately measure at these important levels. To ensure this QC material with similar cut off levels should be employed.

Did you know?

**ISO 15189:2012 recommends the use of** *"The laboratory should choose concentrations of control materials wherever possible, especially at or near clinical decision values, which ensure the validity of decisions made".*

## 4. Peer Group Reporting

In the event of QC failure or rule violation laboratories should have a procedure in place to prevent the release of incorrect patient results. Introducing a peer group reporting program or interlaboratory data management package in your lab can help to detect errors in the analytical phase, automatically applying QC rules and alerting staff to QC failures. Most programmes will also generate a variety of charts and reports, enabling at-aglance performance assessment. Access to peer group data will also assist with the troubleshooting process.

Did you know?

**ISO 15189:2012 recommends the use of** *"The laboratory shall have a procedure to prevent the release of patient results in the event of quality control failure. When the quality control rules are violated and indicate that examination results are likely to contain clinically significant errors, the results shall be rejected.... Quality Control data shall be reviewed at regular intervals to detect trends in examination performance."*

## 5. EQA (External Quality Assessment)

Peer groups are also a key feature of EQA/PT schemes. These schemes will enable you to objectively review the quality of the results the laboratory produces and demonstrate competency in medical diagnostics. EQA/PT, when implemented correctly, exposes unexpected areas of underperformance, allowing you to identify any potential sources of error. The results measured are then compared against peers from other laboratories on regional, national or international levels. ISO 15189:2012 recommends that, as with IQC, EQA/PT schemes *"should provide clinically relevant challenges that mimic patient samples…checking the entire examination process…"*, therefore highlighting the need to use clinically relevant levels in laboratory testing. Look out for international schemes that are accredited to ISO 17043:2010 which make use of frequent reporting and large peer groups. The objective performance assessment that EQA/PT schemes offer compliment your IQC processes and fill in any gaps they may leave behind.

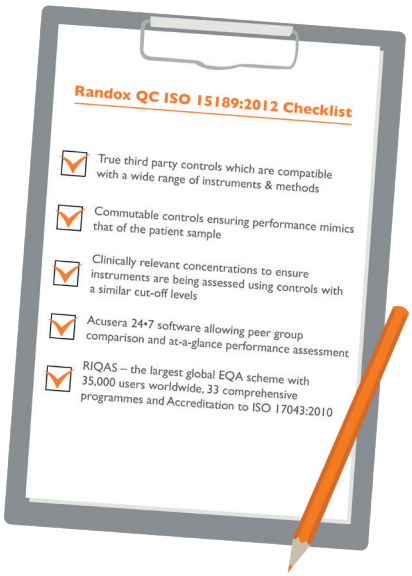
Did you know?

ISO 15189:2012 recommends the use of *"The laboratory shall participate in interlaboratory comparisons such as those organised by external quality assessment or proficiency testing schemes"*

## Conclusion

In order to achieve ISO 15189:2012 Accreditation there are a number of essential considerations to be made. An overall Quality Management plan must be established which encompasses both IQC & EQA to ensure all aspects of laboratory performance are sufficiently covered. To achieve accreditation you must ensure the following is considered; the use of Third Party controls, commutability, clinically relevant levels, Peer Group Reporting and employing an effective EQA scheme. Overall ISO 15189:2012 is increasingly becoming a desired asset in our industry and as such you can be confident that implementing the necessary changes will benefit both your laboratory and the patients.

For more than 30 years Randox has been developing high quality, cost effective quality control solutions for the IVD market. Our internationally renowned Quality Control solutions are guaranteed to simplify QC practice in laboratories of all sizes and budgets. With Acusera, Acusera 24•7 and RIQAS you can be assured that our clinically relevant levels and flexible product offerings will provide innovative QC solutions for results you can trust Furthermore our products can help you gain and maintain ISO 15189:2012 accreditation, meeting the criteria set forth by the standard, further benefitting your laboratory and end users.



# ACUSERA True third party quality controls

As a world leading manufacturer of multi-analyte true third party controls, thousands of laboratories rely on Randox to accurately assess test system performance and ultimately empower them with the confidence required to release patient test results. With more than 390 analytes available, the number of individual controls required to cover your test menu is significantly reduced while simultaneously reducing costs, time and storage space. A choice of formats is available, including liquid or lyophilised, which ensures flexibility and suitability for laboratories of all sizes and budgets. Many features of the Acusera range can help you to meet ISO 15189:2012 requirements:

- Designed to react to the test system in the same manner as a patient sample, helping to reduce inconvenient shifts in QC results when reagent batch is changed and ultimately providing a true indication of laboratory performance.
- The presence of analytes at key decision levels ensures accurate instrument performance and eliminates the need for additional low/high controls at extra expense.
- Manufactured independently from any instrument, the Acusera range delivers unbiased performance assessment with any instrument or method, while eliminating the need for multiple instrument specific controls.

## Product Portfolio

Antioxidants | Blood Gas | Cardiac Markers | Routine Chemistry | Coagulation | Haematology | Diabetes Immunoassay | Immunology | Lipids | POCT | Therapeutic Drugs | Toxicology | Urine Chemistry

Uniquely combining more than 100 analytes conveniently in a single control, laboratories can significantly reduce costs and consolidate without compromising on quality. As true third party controls, unbiased performance assessment with any instrument or method is guaranteed.

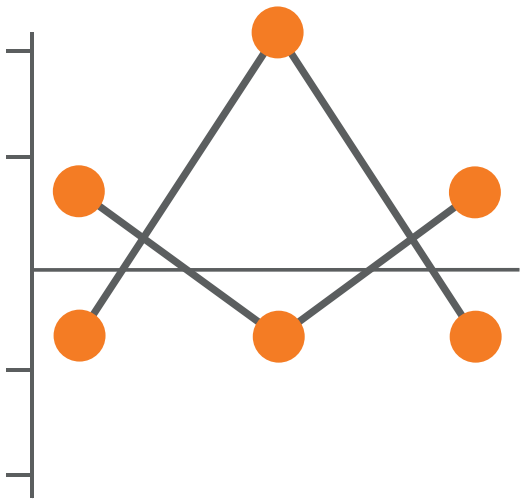
# ACUSERA 24•7 Interlaboratory Data Management

Designed for use with the Acusera range of third party controls, the Acusera 24•7 software helps laboratories monitor and interpret their QC data. Access to an impressive range of features, including interactive charts, the automatic calculation of Measurement Uncertainty & Sigma Metrics and live peer group data generated from our extensive database of laboratory participants, ensures Acusera 24•7 is the most comprehensive package available.

- Advanced statistical analysis with automatic calculation of performance metrics including; Sigma, UM, TE & %Bias.
- Instantly discover how you compare to your peers with peer group statistics updated live in real-time reducing time and money spent troubleshooting.
- Interactive charts allowing you to add events and multiple data sets for quick and easy performance monitoring.
- Automated data import with bi-directional connection to LIMS (eliminating manual data entry).

## Software Features

Dashboard | Result History | Interactive Levey-Jennings Charts | Interactive Histogram Charts
Performance Summary Charts | Statistical Analysis Report | Statistical Metrics Report
Uncertainty of Measurement Report | Exception Report | Peer Group Statistics | Acusera Advisor
Audit Trail Report



'The laboratory shall have a procedure to prevent the release of patient results in the event of quality control failure. When the quality controls rules are violated and indicate that examination results are likely to contain significant errors the results shall be rejected… Quality Control data shall be reviewed at regular intervals to detect trends in examination performance'.

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