RANDOX

EDUCATIONAL GUIDE

Achieving Accreditation with Acusera 24•7

ACUSERA 24·7

At Randox Quality Control, we continuously advocate for the exceptional capabilities of our interlaboratory comparison and peer group reporting software, Acusera 24·7. Those who have experienced it firsthand will understand its value, given its array of engaging, interactive charts and comprehensive, detailed reports that include Measurement Uncertainty, all designed to streamline your QC procedures.

However, Acusera 24·7 offers much more. Our dedicated team is committed to ongoing innovation, enhancing our live, cloud-based software in response to the feedback and needs of our users. With a team that includes experts on accreditation, we actively develop new features to ensure compliance with the standards of various accrediting bodies, including ISO15189, making the process as straightforward as possible for you.

In this guide, we will explore some of the accreditation standards and discuss how the features integrated into Acusera 24·7 are tailored to simplify compliance for our users.

QC management tools in Accreditation

What do the various guidelines have to say about QC management tools? Let's look at some of the major accreditation literature.

ISO15189:2022

The new version of ISO15189 includes updates which aim to place more emphasis on risk management and mitigating risk to the patient. Here's what the 2022 version has to say about QC management tools:

ISO15189:2022 section 7.3.7.2

"e) the resulting data shall be recorded in such a way that trends and shifts are detectable and, where applicable, statistical techniques shall be applied to review the results.

f) IQC data shall be reviewed with defined acceptability criteria at regular intervals, and in a timeframe that allows a meaningful indication of current performance."

The Clinical Laboratory Improvement Amendments 1988 (CLIA)

CLIA '88 regulations are federal standards applicable to all U.S. facilities or sites that test human specimens for health assessment or to diagnose, prevent, or treat disease. These regulations state the following related to QC management:

CLIA Amendments 1988

"Lab surveys by CLIA accreditation bodies will request quality control records including:

a. Remedial action information; …
c. Statistical limits; and
d. Instrument maintenance and function checks records."

4.93.1105 Standard: Retention requirements (a)(3) Analytical system records.

> *"Retain quality control and patient test records (including instrument printouts, if applicable) … for at least 2 years. The records must include charts, graphs, printouts, transcribed data, and manufacturers' assay information sheets for control and calibration materials."*

COLA Accreditation

The Commission on Office Laboratory Accreditation (COLA) is another recognised laboratory accreditation in the U.S. and is a third-party accreditation organisation that ensures laboratories comply with federal regulations, including those set by CLIA.

COLA Accreditation Manual, Section 3 – QC

"Identification of individuals performing QC should be available in the QC records."

"The Surveyor will review QC records, corrective action logs, reagent logs and maintenance or service records to make sure that controls were tested and acceptable. Documentation should include date of testing, initials of the individual performing, actual results and indication of acceptability."

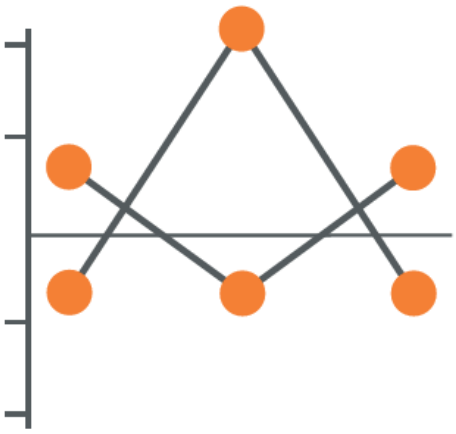
"The Surveyor will look for QC in a graphic format. Data may be graphed as Levey-Jennings Chart or similar graphic representation and reviews of graphs should be performed at least every 5-7 days of testing. The graphs do not have to be printed."

"If there are shifts or trends demonstrated in the data, the Surveyor will expect to see notation by the staff and should be able to follow the documentation trail to corrective action that is taken, as required by the laboratory's QC policies."

"Control charts, graphs, or statistical parameters (i.e. mean, SD and CV) should be maintained for all quantitative tests performed by the laboratory. This data should be reviewed weekly or following every 5-7 data points if performed infrequently to detect changes such as shifts or trends that may be indicators of test system problems that need to be addressed."

"The Surveyor will review QC records for evidence of review – including initials/signature and date of the review. Reviews should take place at least on a monthly basis. If data point(s) fall outside the acceptable ranges, notation, and corrective action, if necessary according to the laboratory's QC procedures, needs to be include in the review.

Corrective actions may include such actions as opening a new bottle of QC, replacing the reagent, or recalibration. Trends and shifts in QC should be noted as well."



Meeting accreditation with Acusera 24·7

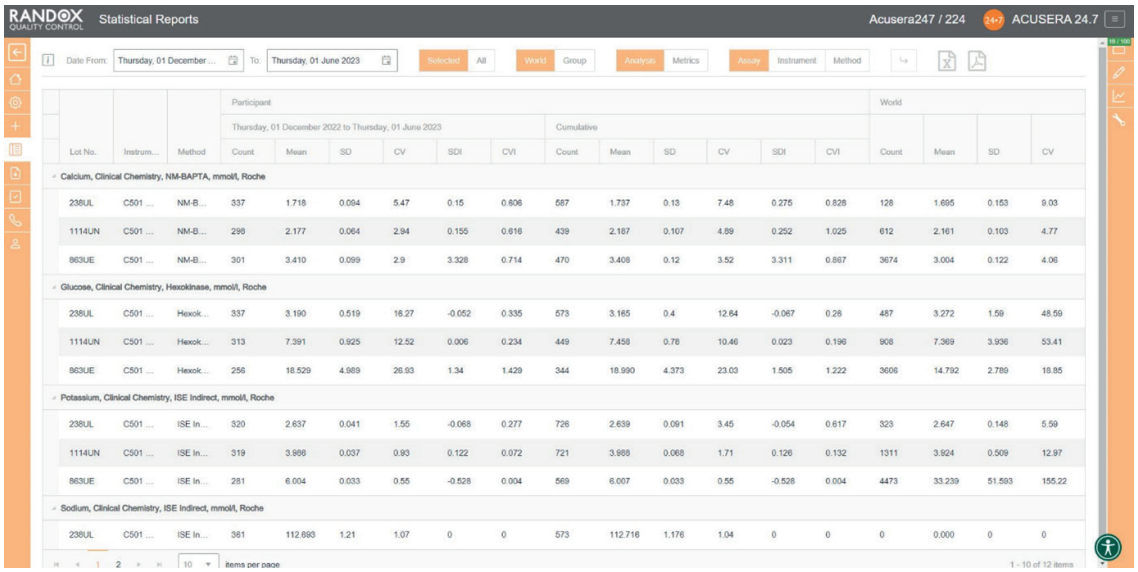
Acusera 24·7 offers a flexible approach to help laboratories meet all the QC accreditation requirements detailed above, including CLIA, COLA, CAP, and ISO15189.

Our user-friendly, cloud-based software allows users to effortlessly run statistical analysis including Coefficient of Variation Index (CVI), Standard Deviation Index (SDI), % Bias, Total Error, Sigma Metrics and more!

Acusera 24·7 can create fully interactive Levey-Jennings charts, and a selection of histograms to provide a wide range of options for the graphical representation of your data. The interactive features of our charts allow you to record events such as lot changes and calibration events directly on to the chart, helping you achieve not just accreditation, but a better understanding of what is going on in your laboratory.

Acusera 24·7 also provides you with a variety of reports to help you effortlessly achieve accreditation. From our Statistical Analysis and Exception reports to our Personalised Performance Summary Reports, we can help your laboratory to efficiently identify and document trends or shifts in performance.

For more information on the features of Acusera 24.7, feel free to read our guide, *Acusera 24·7 – Straightforward QC Data Management and Meeting Accreditation*.



Measurement Uncertainty

Anyone involved in laboratory quality control will be aware of Measurement Uncertainty (MU), although that doesn't mean everyone understands this tricky requirement. MU is defined as a parameter associated with the result of a measurement that characterises the dispersion of values that could reasonably be attributed to the measured quantity.

In other words, MU provides medical laboratories with an estimate of the overall variability in the values they report. The goal of MU is to quantify the doubt or range of possible values around the measurement result, helping to provide an understanding of the reliability and limitations of measurements. This helps ensure measured results are useful and not wildly inaccurate, allows meaningful comparisons with medical decision limits and previous results of the same kind in the same individual and finally, it's a requirement of ISO15189:2022:

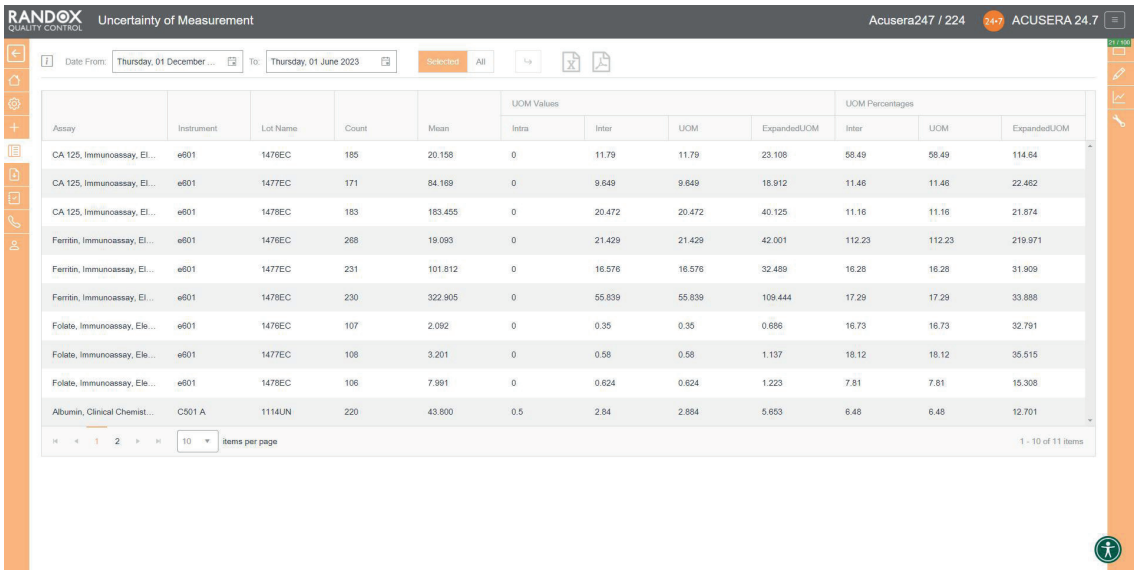
ISO15189:2022 Section 7.3.4

"a. The measurement uncertainty (MU) of measured quantity values shall be evaluated and maintained for its intended use. The MU shall be compared against performance specifications and documented.

b. MU evaluations shall be regularly reviewed."

Calculating MU is no simple task and not one that can even be attempted without in-depth know-how. These calculations can take a single member of staff two full working days to complete. That's a lot of time away from their normal duties, especially if MU is to be reviewed regularly, as per ISO15189:2022.

Lucky for you, Acusera 24·7 can calculate your MU in seconds, rather than days, and provide you with a report. This report can be shown to your accreditation surveyor, and you can consider the MU box ticked. You can read more about Acusera 24.7 and MU in our educational guides *How to Measure Uncertainty and Acusera 24·7 – Straightforward QC Data Management and Meeting Accreditation.*



Peer Group Reporting

The peer group reporting features of Acusera 24·7 are much more than just an added extra. Peer group reporting can help speed up the troubleshooting process, allowing you to determine whether an issue you are seeing is unique to you, or evident in the QC data of you peers. It can also provide you with more confidence in assigned target values and help make significant savings by improving your analytical performance, and therefore, your EQA performance.

A peer group reporting programme can also help meet regulatory requirements, like ISO15189:2022:

ISO15189:2022 Section 7.3.7.3 External quality assessment (EQA)

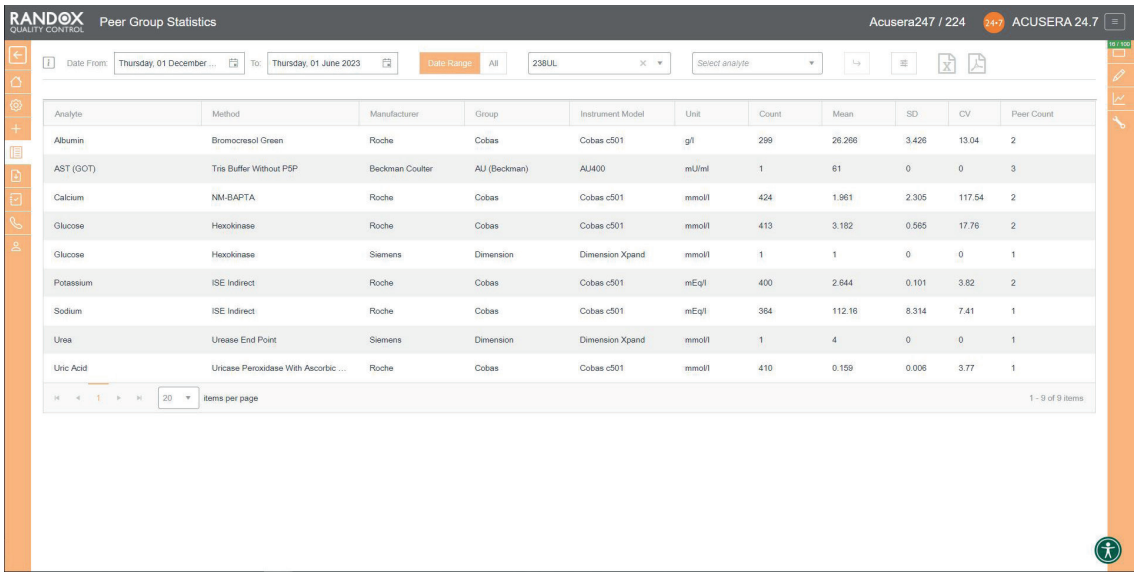
" a. The laboratory shall monitor its performance of examination methods by comparison with results of other laboratories. This includes participation in EQA programmes appropriate to the examinations and interpretation of examination results, including POCT examination methods."

"f. When an EQA programme is either not available, or not considered suitable, the laboratory shall use alternative methodologies to monitor examination methods performance.

NOTE Acceptable alternatives include:

- Interlaboratory comparisons of the results of the examination of identical IQC materials, which evaluates individual laboratory IQC results against pooled results from participants using the same IQC material."

So, if you're struggling to find a suitable EQA programme for your analytes, you might just be able to meet your accreditation with the peer group reporting features included in Acusera 24·7.



Elevating Laboratory Standards with Acusera 24.7

In the rapidly evolving field of laboratory medicine, Acusera 24·7 stands as a pivotal tool for laboratories aiming to surpass the stringent demands of accreditation. By integrating cutting-edge features such as real-time peer group reporting, automated MU calculations, and comprehensive statistical analyses, Acusera 24·7 not only meets but often exceeds the criteria set by major accreditation bodies, including ISO15189, CLIA, and COLA.

The efficiency brought about by Acusera 24·7 transforms the daunting task of accreditation into a streamlined process, enabling laboratories to maintain continuous compliance and improve quality control measures. The software's intuitive design and sophisticated capabilities provide unparalleled support for laboratories, ensuring that they can focus on what truly matters—delivering accurate and reliable results that enhance patient care.

As we look to the future, the role of technologies like Acusera 24·7 in laboratory accreditation will become increasingly significant. Embracing these tools can significantly bolster a laboratory's ability to adapt to new regulations, enhance operational efficiency, and ultimately, achieve higher standards of diagnostic accuracy.

For laboratories committed to achieving and maintaining the highest standards of operational excellence and regulatory compliance, Acusera 24·7 offers not just a solution but a transformative strategy that ensures success in the demanding arena of medical laboratory testing.

RANDOX QC PORTFOLIO

ACUSERA - True Third Party Controls Offering Complete Test Menu Consolidation

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 - Online QC Software With Real-Time Peer Group Statistics

Designed for use with the Acusera range of third party controls, the Acusera 24•7 software will help you monitor and interpret your 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.

RIQAS - Randox International Quality Assessment Scheme

The largest international EQA scheme, used by more than 76,000 laboratory participants in over 139 countries worldwide. Comprising over 360 routine and esoteric parameters in 35 comprehensive and flexible EQA programmes, RIQAS is designed to cover all areas of clinical testing. Each programme benefits from a wide range of concentrations, frequent reporting and informative yet user-friendly reports.

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