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Importance of Comprehensive Chemistry Knowledge in Quality Management for Laboratory Regulatory Activities

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Abstract

Chemistry knowledge is fundamental to effective quality management and regulatory oversight of testing, calibration, environmental, industrial, pharmaceutical, food, medical, research and other analytical laboratories. Laboratory regulatory activities require more than document verification and administrative compliance; they require competent evaluation of scientific principles, analytical methods, sampling, instrumentation, reference materials, measurement uncertainty, quality control, data integrity and laboratory safety. Comprehensive chemistry knowledge enables inspectors and technical assessors to evaluate chemical reactions, matrix effects, interference, detection capability, analytical sensitivity, accuracy, precision and other factors affecting measurement reliability. ISO/IEC 17025:2017 establishes internationally recognized requirements for laboratory competence, impartiality and consistent operation. Eurachem guidance emphasizes fitness for purpose, method validation and verification, sampling, sample handling and analytical performance characteristics. Effective regulatory assessment therefore requires knowledge of general, analytical, physical, organic and inorganic chemistry, instrumental analysis and metrology. It also requires competence in quality assurance, quality control, proficiency testing, chemical safety and data integrity. These technical capabilities enable regulators to determine whether analytical results are scientifically valid, traceable and fit for their intended regulatory purpose. This paper examines the role of comprehensive chemistry knowledge in laboratory quality management and regulatory inspection and proposes a competency framework for regulatory personnel. Ultimately, effective laboratory regulation depends on the integration of scientific competence, robust quality management and independent, evidence-based regulatory decision-making.

Keywords: Chemistry knowledge, Laboratory regulation, Regulatory oversight, and Quality management.

1. Introduction

Laboratories provide scientific measurements that are used to determine whether products, materials, environmental samples and other regulated substances comply with established requirements. Consequently, the credibility of regulatory systems depends strongly on the reliability, accuracy and traceability of laboratory results (ISO & IEC, 2017). Laboratory regulatory activities include licensing, authorization, inspection, accreditation oversight, technical

assessment, surveillance, enforcement and evaluation of laboratory performance. These activities require both management-system knowledge and technical competence. ISO/IEC 17025:2017 specifically establishes requirements for laboratory competence, impartiality and consistent operation and is used as a basis for assessing and accrediting testing and calibration laboratories (ISO & IEC, 2017).

Chemistry is fundamental to a wide range of laboratory activities because chemical measurements are influenced by the interactions among analytes, sample matrices, reagents, analytical instruments and environmental conditions. Effective regulatory assessment therefore requires sufficient chemistry knowledge to evaluate whether laboratory procedures, analytical methods and measurement processes are scientifically sound and technically valid. The reliability of laboratory results depends on several interconnected factors, including sampling, method selection, calibration, analytical performance, recovery, detection capability, measurement uncertainty and control of potential interferences. Proper evaluation of these factors requires a sound understanding of analytical chemistry and measurement science. Eurachem's current method-validation guidance addersses fitness for purpose, method validation and verification, sampling and sample handling, detection limits, precision, trueness, recovery, working range and other relevant analytical performance characteristics (Almoghames *et al*., 2023; Cantwell, Helen, 2025).

Accordingly, comprehensive chemistry knowledge should be regarded as a core technical competency for personnel involved in laboratory regulatory activities, quality assessment, inspection and technical evaluation.

Scope of Chemistry Knowledge for Laboratory Regulatory Activities

Chemistry knowledge required for regulatory oversight is multidisciplinary. It includes fundamental chemistry as well as specialized analytical and measurement sciences. Three basic aspects of chemistry knowledge provide fundamental understanding of regulatory oversight is mentioned in **Fig. 1**.

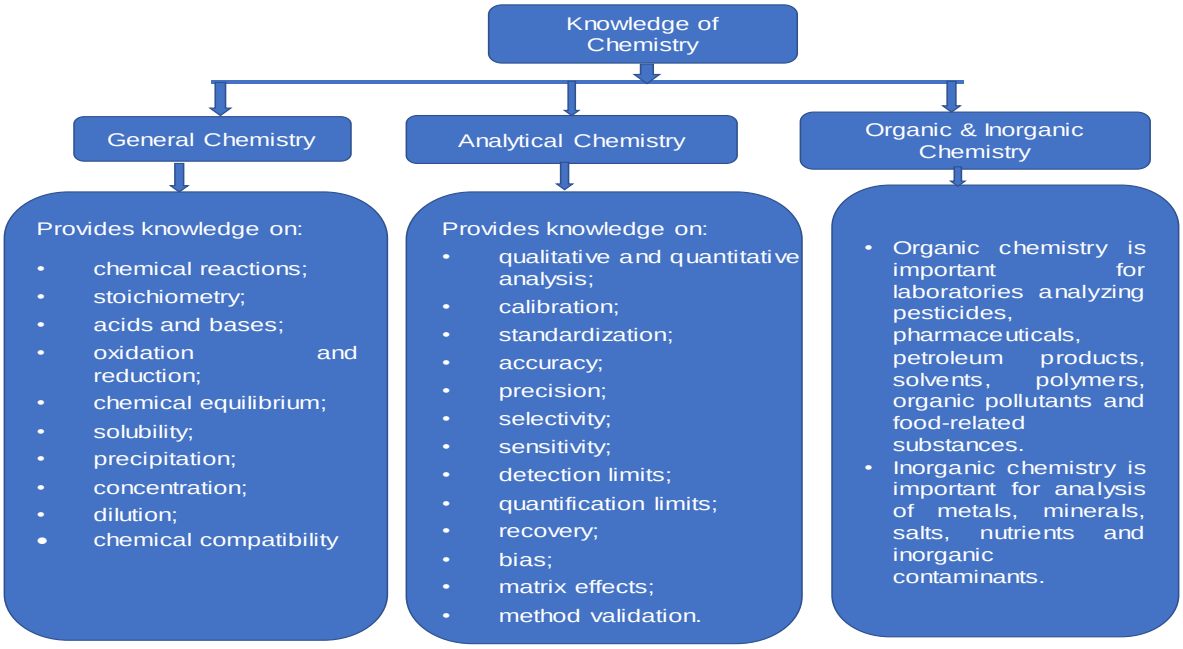

Fig. 1: Basic aspects of chemistry knowledge.

General chemistry is essential for regulators to assess laboratory procedures, calculations, and reagent preparation. Analytical chemistry is particularly important for evaluating the reliability, accuracy, and suitability of measurement methods for regulatory purposes. Understanding chemical species is also crucial, as the behavior and properties of an element or compound can vary with its chemical form.

Chemistry Knowledge and Quality Management

A laboratory quality management system provides a structured framework for controlling activities and ensuring reliable results. However, quality management cannot replace scientific competence. ISO/IEC 17025:2017 combines management-system requirements with technical requirements because laboratory quality depends on both effective management and technically valid operations (ISO & IEC, 2017).

Chemistry knowledge enables regulatory personnel to determine whether:

1. the analytical method is scientifically appropriate;
2. the laboratory has competent analysts;
3. reagents and standards are suitable;
4. instruments are properly calibrated;
5. samples are representative;
6. quality-control procedures are appropriate;
7. analytical results are technically valid.

Thus, chemistry and quality management are complementary. A documented procedure may satisfy an administrative requirement, but a technically competent regulator must also determine whether the procedure is scientifically justified.

Importance of Sampling and Sample Handling

Sampling is one of the most important stages of laboratory testing. The reliability of an analytical result depends not only on the analytical method but also on whether the sample represents the material or environment under investigation. Eurachem's 2025 method-validation guide specifically includes sampling and sample handling in relation to validation and analytical fitness for purpose (Cantwell, Helen, 2025). Regulatory assessment should therefore evaluate the sampling and sample-handling process, including:

- Sampling plans: scientific justification, scope and representativeness of the sampling strategy.
- Sampling locations: suitability of sampling points for obtaining representative samples.
- Sampling frequency: adequacy of sampling intervals for the intended regulatory purpose.
- Sample quantity: sufficiency of sample volume or mass for the required analyses and quality-control measurements.
- Sample containers: suitability, cleanliness, compatibility and contamination control of containers.
- Sample preservation: appropriate measures to maintain sample integrity and analyte stability.
- Transportation: controlled conditions to prevent contamination, degradation or alteration during transit.
- Storage: appropriate temperature, environmental conditions and maximum holding times before analysis.
- Sample identification: unique labelling and traceability from collection through analysis and reporting.
- Chain of custody: documented control and accountability for sample handling, transfer and analytical processing.

Chemical changes can occur between collection and analysis through oxidation, reduction, volatilization, adsorption, precipitation or biological activity. Consequently, inappropriate sample handling can produce an incorrect result even when the analytical instrument operates correctly. Knowledge on chemistry enables inspectors to recognize these potential changes and determine whether appropriate controls have been established.

Analytical Method Selection and Validation

An analytical method should be scientifically appropriate and fit for its intended regulatory purpose. Regulatory assessment should verify that the laboratory has demonstrated adequate method performance through appropriate validation or verification. Here, key performance character includes selectivity, working range, analytical sensitivity, precision, recovery, detection capability and robustness (Cantwell, Helen, 2025).

Accuracy: The method should provide results sufficiently close to an accepted reference value, with bias assessed using suitable reference materials or comparison studies.

Precision: Acceptable agreement among repeated measurements under defined conditions, including repeatability and intermediate precision should demonstrate in the method.

High precision alone does not ensure validity if significant systematic bias is present.

Selectivity: The method should reliably distinguish the analyte from interfering substances within the sample matrix.

Detection and Qualification Limits: Adequate detection and quantification capability relative to applicable regulatory requirements. should be demonstrated in the method.

Recovery and Robustness: The laboratory should establish acceptable analyte recovery and demonstrate that the method remains reliable under controlled variations in relevant conditions.

Overall, regulatory evaluation should confirm that the validated method is capable of producing reliable, traceable and fit-for-purpose results (Cantwell, Helen, 2025).

Instrumental Analysis and Calibration

Modern laboratories use advanced instruments such as UV-visible spectrophotometers, AAS, ICP-OES, ICP-MS, GC, and LC. They also use mass spectrometers, ion chromatographs, XRF, and electrochemical instruments. Regulatory personnel do not need to operate every instrument themselves. However, they should understand the principles and limitations of the techniques used. They should also recognize the major sources of analytical error. Important considerations include instrument qualification and proper calibration. Calibration verification is necessary to confirm that instruments remain accurate. Regular maintenance and suitable environmental conditions are also essential. Regulators should consider instrument drift, reference standards, and software controls. The measurement range and detection capability of an instrument must also be assessed. ISO/IEC 17025 requires laboratories to demonstrate technical competence and control equipment (ISO & IEC, 2017). Knowledge of chemistry helps regulators identify results that appear reasonable but may be scientifically unreliable.

Measurement Uncertainty and Metrological Traceability

No measurement is perfectly exact. Laboratory results are associated with measurement uncertainty. Sources of uncertainty may include sampling, weighing, volumetric operations, calibration, instrument resolution, repeatability, environmental conditions, reagent purity, reference materials, and analyst effects. The Eurachem/ CITAC Guide Quantifying Uncertainty in Analytical Measurement, 3rd edition, provides guidance for evaluating uncertainty in chemical measurements and emphasizes integration of uncertainty evaluation with laboratory quality-assurance activities (Ellison, S. L. R. & Williams, A., 2012). Measurement uncertainty becomes especially important when a test result is close to a regulatory limit. ILAC G17:01/2021 provides guidance on the evaluation and reporting of measurement uncertainty in testing in relation to ISO/IEC 17025:2017 (ILAC, 2021). Metrological traceability is also important because it establishes confidence that measurement results can be related to appropriate references through a documented calibration chain (BIPM, OIML, ILAC, & ISO, 2018).

Quality Assurance and Quality Control

Quality assurance provides confidence that laboratory processes are systematically controlled, while quality control provides evidence that individual analytical processes are performing acceptably. Important QC activities include blanks, duplicate and spiked samples, recovery studies, control samples, reference materials, calibration verification, replicate measurements, and control charts. Repeated recovery outside the acceptance range may indicate matrix effects, reagent or instrument problems, analyst errors, sample preparation issues, or method limitations; regulators should determine the cause. QC results are actively evaluated rather than simply recorded. Chemistry knowledge allows the regulator to investigate the scientific significance of these observations. Eurachem's current guidance recognizes the use of method-performance data in internal quality control and emphasizes appropriate follow-up after validation (Azam *et al.*, 2026; Cantwell, Helen, 2025).

Reference Materials and Laboratory Traceability

Reference materials are important tools for evaluating analytical accuracy and maintaining measurement consistency. A regulatory assessor should assess the

reference material's certification, source, assigned value, uncertainty, traceability, expiry, storage conditions, and preparation. Certified reference materials provide an independent means of checking analytical performance. Where laboratories prepare working standards from stock solutions, regulators should assess the preparation calculations, purity of starting materials, volumetric equipment, storage conditions and stability. These activities require both chemistry knowledge and metrological understanding.

Proficiency Testing and Inter-laboratory Comparison

Proficiency testing provides an independent mechanism for evaluating laboratory performance. A laboratory analyses a test sample and its result is compared with an assigned or consensus value. Regulatory assessors should review:

- participation in appropriate proficiency-testing programmes;
- frequency of participation;
- performance history;
- unsuccessful results;
- root-cause investigations;
- corrective actions;
- evidence of effectiveness.

ILAC guidance identifies proficiency testing and related external quality-assurance mechanisms as important elements of demonstrating laboratory competence (ILAC, 2021). Repeated unsatisfactory performance should trigger appropriate investigation and regulatory attention.

Chemical Safety and Laboratory Regulatory Oversight

Laboratories may handle corrosive, toxic, flammable, oxidizing, reactive, and other hazardous chemicals. Common examples include concentrated acids, strong alkalis, organic solvents, and toxic metals. They may also use oxidizing agents, compressed gases, carcinogenic substances, and reactive chemicals. Regulatory inspections should assess whether chemicals are stored safely and appropriately (Barwick, Vicki & Tsimillis, Kyriacos C., 2023; ISO & IEC, 2017). Proper segregation of incompatible chemicals is essential to prevent dangerous reactions. Inspectors should also check chemical labeling and compatibility requirements. Adequate ventilation should be available when handling hazardous substances. Spill response measures and emergency procedures should be clearly established. Appropriate personal protective equipment should be provided and used. Chemical inventories should be maintained accurately and kept up to date. Safe chemical waste management and disposal practices should also be evaluated. Chemistry knowledge is essential because some chemical incompatibilities and reaction hazards cannot be identified through document review alone (Barwick *et al*., 2023; ILAC, 2024) .

Data Integrity and Technical Records

Laboratory results may support regulatory enforcement, licensing, product approval, and environmental decisions, making data integrity essential. Laboratory records should contain sufficient information to reconstruct the complete analytical process. Regulators should review raw data, calculations, instrument records, and calibration records (Barwick, Vicki & Tsimillis, Kyriacos C., 2023; ISO & IEC, 2017). Chromatograms, spectra, sample identification, and analyst identification should be properly documented. Corrections to records should be traceable, justified, and appropriately controlled. Electronic audit trails and data-retention practices should also be examined. Technical records should provide reliable evidence that reported results are supported by the analytical data (ISO & IEC, 2017). Chemistry knowledge helps regulators determine whether reported results are scientifically plausible and consistent with raw evidence. Unusual patterns, such as improbable precision or unexplained identical results, should be investigated. Inconsistent dilution factors or results that conflict with known sample characteristics may indicate data or analytical problems (Barwick, Vicki & Tsimillis, Kyriacos C., 2023; ILAC, 2024).

Regulatory Inspection of Laboratories

Laboratory regulatory inspection should combine management-system assessment with technical evaluation. A comprehensive inspection can be structured around the following areas are shown in **Table 1**. ISO/IEC 17025 applies both management-system and technical requirements, with technical requirements needing to reflect the specific field of testing performed (ISO & IEC, 2017).

Table 1: Inspection area and key elements to evaluate a comprehensive inspection.

Inspection area	Key Elements to Evaluate
Management System	Quality policy; document control; internal audits; management review; corrective actions
Personnel	Qualifications; training; competence; authorization; continuing professional development
Facilities and Equipment	Environmental conditions; equipment suitability; maintenance; calibration; contamination control
Sampling and Testing	Sampling; sample receipt; preparation; analytical procedures; calculations; reporting
Quality Assurance	QC samples; proficiency testing; reference materials; measurement uncertainty; data review

Therefore, inspection teams should include personnel with appropriate technical expertise for the laboratory's scope.

Chemistry Knowledge in Regulatory Decision-Making

Laboratory regulation ultimately aims to support scientifically sound and defensible decisions. Chemistry knowledge helps regulatory personnel evaluate the reliability of analytical evidence. It enables them to identify inappropriate analytical methods and correctly interpret chemical results. Regulators should understand measurement uncertainty and distinguish systematic from random errors. They should also assess compliance with regulatory limits and specifications. The significance of analytical deviations should be evaluated carefully. Regulators should determine whether corrective actions adequately address identified problems. Decision rules are especially important when analytical results are compared with regulatory limits. ILAC G8:09/2019 provides guidance on decision rules and statements of conformity relevant to assessors and regulators (ILAC, 2019). Therefore, regulators should consider the reported result, measurement uncertainty, and applicable decision rule before making a conformity decision.

Corrective Action and Root-Cause Analysis

Laboratory deficiencies may include calibration failures, unacceptable QC results, contamination, sample preparation errors, and inappropriate analytical methods. Other causes may include analyst error, inadequate training, reagent deterioration, and instrument malfunction. The laboratory should investigate the underlying cause and implement appropriate corrective action (ISO & IEC, 2017). The regulatory assessor should evaluate:

Nonconformity → Immediate Correction → Root Cause → Corrective Action → Effectiveness Verification.

Chemistry knowledge helps determine whether the proposed root cause is scientifically credible. For example, repeated recalibration may temporarily correct biased instrument results without addressing the underlying problem.

Competency Requirements for Regulatory Chemistry Personnel

A regulatory organization should establish a competency framework that covers both scientific expertise and regulatory capabilities. The following levels are recommended in **Table 2**.

Table 2: Competency level required for regulatory personnel.

Competency area	Recommended level	Competency area	Recommended level
General chemistry	Advanced	Instrumental analysis	Advanced
Analytical chemistry	Advanced	Sampling	Advanced
Organic chemistry	working	Method validation	Advanced
Inorganic chemistry	Advanced	Calibration	Advanced
Physical chemistry	Working/Advanced	Measurement uncertainty	Advanced
Quality assurance/ Quality control (QA/QC)	Advanced	Reference materials	Advanced
Proficiency testing	Advanced	Data integrity	Advanced
Chemical safety	Advanced	Laboratory inspection	Advanced
Root-cause analysis	Advance	Regulatory assessment	Advanced
Technical reporting	Advanced		

Competence should be maintained through formal education, technical training, supervised laboratory assessments, continuing professional development (CPD), and periodic competency reassessment. This ensures that regulatory personnel remain scientifically competent and capable of making reliable, evidence-based regulatory decisions.

2. Conclusion and Recommendations

Comprehensive chemistry knowledge is essential for effective quality management and regulatory oversight of laboratory activities. Laboratory regulation is fundamentally a scientific process requiring technically competent personnel capable of evaluating and challenging analytical evidence. Chemistry knowledge is essential throughout the laboratory workflow, from sampling and preservation to analysis, calibration, quality control, uncertainty evaluation and reporting. It encompasses general, analytical, organic, inorganic and physical chemistry, instrumental analysis, metrology, environmental chemistry and chemical safety. These disciplines provide the scientific basis for assessing the validity, reliability and fitness-for purpose of laboratory results. ISO/IEC 17025:2017 establishes an internationally recognized framework for laboratory competence, impartiality and consistent operation (ISO & IEC, 2017). Eurachem guidance emphasizes method fitness for purpose, validation, verification, sampling, sample handling and analytical performance assessment (Cantwell, Helen, 2025). Eurachem/CITAC and ILAC guidance further support the evaluation of measurement uncertainty, traceability and conformity decisions (Ellison, S. L. R. & Williams, A., 2012; ILAC, 2019, 2021). However, compliance with standards alone cannot ensure technically reliable laboratory results. Effective regulatory oversight requires personnel with sufficient chemistry and measurement-science competence to evaluate the underlying analytical processes. The fundamental relationship can therefore be expressed as:

Chemistry Knowledge → Technical Competence → Reliable Results → Effective Quality Management → Scientifically Defensible Regulatory Decisions.

Strengthening chemistry competence within regulatory organizations will improve laboratory inspections, enhance confidence in analytical results and support robust compliance and enforcement decisions. Ultimately, scientifically competent laboratory regulation contributes to the protection of public health, consumers, workers and the environment.

The following measures are recommended to strengthen chemistry-based quality management in laboratory regulatory activities:

1) Establish chemistry and analytical science as core competencies for regulatory assessors.
2) Implement competency-based training in analytical chemistry, instrumentation, method validation, QA/QC, metrology and inspection.
3) Strengthen regulatory oversight of sampling, sample handling and analytical method validation.
4) Ensure appropriate evaluation of measurement uncertainty, traceability and calibration systems.
5) Use proficiency testing, reference materials and QC data as evidence of laboratory competence.
6) Incorporate data integrity and chemical safety into laboratory inspections.
7) Apply risk-based inspection to prioritize high-consequence laboratory activities.
8) Maintain records of nonconformities, recurring deficiencies and corrective actions to support regulatory learning.
9) Provide continuous professional development for regulatory chemistry personnel.
10) Apply independent technical review and appropriate decision rules for complex or high-consequence analytical results, considering measurement uncertainty.

3. Author Contributions

S.A.: contributed to the conceptualization of the review, literature search, analysis of relevant studies and manuscript writing. F.H.: contributed to revising the manuscript. Both authors reviewed the manuscript, approved the final version, and agreed to be accountable for the content of the work.

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5. Conflicts of Interest

The authors declare that they have no conflicts of interest related to this research study.

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