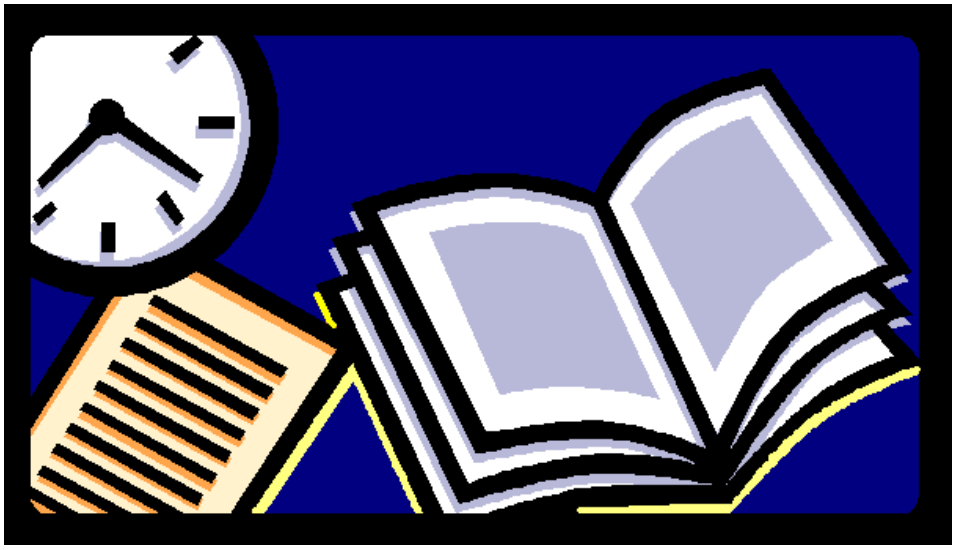
Micro Metrology, inc.
Accredited Calibration Laboratory
www.mmicallabs.com



Quality Manual

Quality Manager: Greg Ganner

President / CEO: Allen Ganner

Date of Issue: 2001/08/03

Controlled Copy #: 1M

Quality Manual

This Quality Manual meets the requirements of ISO 17025 and ISO 9001. This Quality Manual is confidential and assigned as outlined below.

Document Control

Issue Date : _____

Issued To: _____

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Copy No: _____

Adoption

Micro Metrology Inc. Quality Manual

Issued under the authority of the President / CEO

Adopted By: *Allen Ganner*

Title / Position : President / CEO

Signature: _____

Date: _____

Table of Contents

Introduction – the READ ME page!

Purpose

This Quality Manual contains all the requirements that our laboratory uses to demonstrate our quality system, technical competence, and valid results.

Section 4 specifies how we demonstrate sound management and maintain client satisfaction.

Section 5 specifies how we demonstrate technical competence in our laboratory.

In addition, this Quality Manual outlines how we meet:

- ISO 17025
- ISO 9001

All personnel are to take an active role in establishing, implementing, and maintaining our quality management program. We do not separate quality from our daily business. Quality cannot be something that we do just to pass audits. Quality is involved in every facet of the decision-making process in the management of our laboratory and the science that we practice.

Distribution List

The Quality Manager maintains a distribution list for this Quality Manual.

1. Scope

This Quality Manual facilitates:

- recognition of technical competence for standardized methods, non-routine methods, and laboratory-developed methods we perform
- inspection and product certification capabilities and/or services we provide
- total quality for our administrative and technical systems
- audits by clients, regulatory authorities and accreditation bodies
- meeting the requirements of ISO 17025 and ISO 9001
- client satisfaction

2. Normative References

Reference List

ISO/IEC Guide 2 - *General Terms and Their Definitions Concerning Standardization and Related Activities*.

VIM: 1993 – *International Vocabulary of Basic and General Terms in Metrology*, Issued by BIPM, IEC, IFCC, ISO, IUPAC, IUPAP and OIML.

ISO 9001:2000 – *Quality Management Systems – Requirements*.

ISO 17025:1999 – *General Requirements for the Competence of Testing and Calibration Laboratories*.

ANSI/NCSL Z540-1, 1994, *Calibration Laboratories and Measuring and Test Equipment – General Requirements*

ISO/IEC Guide 25, 1990, Third Edition, *General Requirements for the Competence of Calibration and Testing Laboratories*

NIST HB 145, 1986, *Handbook for the Quality Assurance of Metrological Measurements.* John K. Taylor and Henry V. Opperman

NIST Technical Note 1297, 1994, *Guidelines for Evaluating and Expressing the Uncertainty of NIST Measurement Results.* Barry N. Taylor and Chris E. Kuyatt

National Conference of Standards Laboratories (NCSL), 1993, *Recommended Practice (RP) No. 7, Laboratory Design*

Cross-references

This manual is numerically aligned with the international standard ISO 17025. It is expected that this will prove useful during accreditation audits and expedite the process.

Furthermore, each section cross-references the ISO 9001 standard to assist the laboratory during the ISO 9001 registration process (if applicable).

For ease of use, each section starts with a brief summation of what the section addresses and a listing of the quality terminology and key words.

3. Terms and Definitions

For the purposes of this manual, the following relevant definitions apply: ISO/IEC Guide 2; ISO/IEC Guide 30; ISO Council Committee on Conformity Assessment (CASCO); ISO 8402; ISO 10015; ISO 5725-1; ISO 17025; the Food Laboratory Accreditation Working Group (FLAWG); AOAC; American Chemical Society (ACS); and International Vocabulary of Basic and General Terms in Metrology (VIM).

Accreditation – formal recognition of a laboratory by an independent science-based organization that the laboratory is competent to perform specific tests (CASCO).

Accuracy – the closeness of agreement between a test result and the accepted reference value (ISO 5725-1, ISO Guide 30).

Calibration - a set of operations that establish, under specified conditions, the relationship between values of quantities indicated by a measuring instrument or measuring system or values represented by a material measure or a reference material, and the corresponding values realized by the standard (VIM).

Notes

1. The result of a calibration permits either the assignment of values or measurands to the indications or the determination of corrections with respect to indications.
2. A calibration may also determine other metrological properties such as the effect of influence quantities.
3. The result of a calibration may be recorded in a document sometimes called a calibration certificate or a calibration report.

Certification - procedure by which a third party gives written assurance that a product, process, or service conforms to specified requirements (ISO 8402).

Certified Reference Material – a reference material, one or more of, whose property values are certified by a technically valid procedure, accompanied by or traceable to a certificate or other documentation which is issued by a certifying body (ISO Guide 30).

Client – an entity (customer, agency, company, person, etc.) who receives a test result done according to specified requirements (FLAWG).

Competence – ability consisting of theoretical knowledge, practical skills, and attitudes (ISO 10015).

Corrective Action – action taken to eliminate the causes of an existing nonconformity, defect, or other undesirable situation in order to prevent recurrence (ISO 8402).

Holding Time – elapsed time between sample collection and either sample preparation or analyses, as appropriate.

Inspection - evaluation for conformity by measuring, observing, testing, or gauging the relevant characteristics (ISO/IEC Guide 2). Activity such as measuring, examining, testing or gauging one or more characteristics of an entity and comparing the results with specified requirements in order to establish whether conformity is achieved for each characteristic. (ISO 8402)

Limit of Detection – the minimum concentration of a substance that can be measured and reported with 99% confidence that the analyte concentration is greater than zero and is determined from the analysis of a sample in a given matrix containing the analyte (ACS). The mean value of the matrix blank readings plus 3 standard deviations of the mean, expressed in analyte concentration. For methods with less than 100% recovery the limit of detection should be corrected for recovery (AOAC).

Limit of Quantification – lowest concentration of analyte that can be determined with an acceptable level of accuracy and precision. Determined by actual analysis of at least 6 fortified test samples per matrix. It is not determined by extrapolation (AOAC).

Linearity – is determined by the analysis of samples with analyte concentrations spanning the claimed range of the method. The results are used to calculate a regression line against analyte calculation using the least squares method. It is convenient if a method is linear over a particular range but it is not an absolute requirement. Where linearity is unattainable for a particular procedure, a suitable algorithm for calculations should be determined (AOAC).

Measurement Uncertainty - parameter, associated with the result of a measurement that characterizes the dispersion of the values that could reasonably be attributed to the measurand (International Vocabulary of Basic and General Terms in Metrology).

Precision – the closeness of agreement between test results obtained under stipulated conditions (ISO 5725-1, ISO Guide 30).

Preventive Action – action taken to eliminate the causes of a potential nonconformity, defect, or other undesirable situation in order to prevent occurrence (ISO 8402).

Proficiency Testing – determination of the laboratory calibration or testing performance by means of inter-laboratory comparisons (ISO/IEC Guide 2).

Quality Assurance – all those planned and systematic actions necessary to provide adequate confidence that a product or service will satisfy given requirements for quality (ISO 8402).

Quality Control – the operational techniques and activities that are used to fulfill requirements for quality (ISO 8402).

Quality Manual – a document stating the quality policy, quality system, and quality practices of an organization (ISO 8402).

Quality System – the organizational structure, responsibilities, procedures, processes, and resources for implementing quality management (ISO 8402).

Range – the difference between the largest and smallest observed value of a quantitative characteristic. For quantitative analysis the working range for a method is determined by examining samples with different analyte concentrations and determining the concentration range for which acceptable accuracy and precision can be achieved. The working range is generally more extensive than the linear range. The working range is determined by the analysis of a number of samples of varying analyte concentrations and calculating the regression from the results, usually using the method of least squares. The relationship of analyte response to concentration does not have to be perfectly linear for a method to be effective (AOAC).

Reference Material – a material or substance one or more properties of which are sufficiently well established to be used for the calibration of an apparatus, the assessment of a measurement method, or for assigning values to materials (ISO Guide 30).

Reference Standard – a standard, generally of the highest metrological quality available at a given location, from which measurements made at that location are derived (VIM). Generally, this refers to national traceable standards such as those from the National Institute of Standards and Technology (NIST).

Repeatability (r) – precision under the *same conditions* (same method, same test item, same operator, same apparatus, same laboratory, short interval of time) (ISO 5725-1).

Reproducibility (R) – precision using the *same method* on identical items obtained by operators in different laboratories using different equipment (ISO 5725-1).

Ruggedness – the ruggedness of a method is tested by deliberately introducing small changes to the method and examining the consequences. A large number of factors may need to be considered, but because most of these will have a negligible effect, it will normally be possible to vary several at once (AOAC).

Selectivity – the extent that a specific analyte can be determined from a complex mixture without interference from the other components in the mixture. A method that is perfectly selective for an analyte or group of analytes is said to be specific. The applicability of the method should be studied using various samples, ranging from pure standards to mixtures with complex matrices. In each case the recovery of the analyte(s) of interest should be determined and the influences of suspected interference duly stated. Any restrictions in the applicability of the technique should be documented in the method (AOAC).

Sensitivity – the difference in analyte concentration corresponding to the smallest difference in the response of the method that can be detected. It is represented by the slope of the calibration curve and can be determined by a least squares procedure, or experimentally, using samples containing various concentrations of the analyte (AOAC).

Skill – ability to apply knowledge effectively and readily in performance (ISO 10015).

Specific – see selectivity.

Standard Operating Procedure – a document that specifies or describes how an activity is to be performed. It may include methods to be used and sequence of operations (FLAWG).

Test - technical operation that consists of the determination of one or more characteristics of a given product, process, or service according to a specified procedure (ISO Guide 2: 1991).

Traceability – the property of a result of a measurement whereby it can be related to appropriate standards, generally international or national standards, through an unbroken chain of comparisons (VIM).

Training – a process to provide and control competence to meet requirements (ISO 10015).

Validation - confirmation by examination and provision of objective evidence that the particular requirements for a specific intended use are fulfilled (ISO 8402).

Verification - confirmation by examination and provision of objective evidence that specified requirements have been fulfilled (ISO 8402).

4.1 Organization

The Ten Second Tutorial

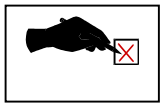
This section tells you our laboratory has:

1. Appointed a Quality Manager
2. Organized the workforce to achieve quality
3. Provided adequate resources to ensure quality

Key Words

Quality Manager
Organizational Chart
Authority
Resources
Confidential Information
Proprietary Rights
Responsibilities
Undue Pressure

Cross-references



ISO 17025:1999 Section 4.1
ISO 9001:2000 Section 5.1, 5.3, 5.4.1, 5.5.1, 5.5.2, 6.1, 6.2.1, 6.3

4.1.1 Legal Identification / Registration

Micro Metrology Inc.
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Tel: (818) 993-4971
Fax: (818) 701-5516

4.1.2 Laboratory Requirements

The executive offices / departments / units / laboratories / work areas of Micro Metrology Inc. have been organized to satisfy the needs of the client and regulatory authorities and to operate to the international standards ISO 17025 and ISO 9001. Micro Metrology Inc. is composed of the following executive offices and their respective subordinate departments / units / laboratories / work areas:

President / CEO's Office (General Management)
Executive Vice-President (Comptroller / Accounting Dept. / Administrative Support Unit / Information Management Systems)
Senior Vice-President, Operations (Corp. Metrologist / Technical Manager / Metrology Engineering / Laboratory Operations / Shipping & Receiving Area)
Vice-President, Marketing & Sales (Sales Dept. / Marketing & Advertising Unit)
Vice-President, Business Development (Internet Business Unit / Alliances & Affiliations)
Quality Manager (Total Quality & Continuous Process Improvement Dept.)

4.1.3 Scope of Management System

The management system covers activities in the laboratory's permanent facility, field service (customer site) calibration, and transportable field calibration unit (TFCU). The fields of activities include:

Calibration, Verification & Repair Services [Permanent facility / field (customer site) calibration / TFCU]
Metrology Engineering Consultation
Product Testing [Excluding Non-Destructive Testing (NDT) / Analytical Research]
Test & Measurement Equipment Sales, Distribution & Service

The laboratory's scope of tests is listed in but not limited to the Measurement Parameters declared in Appendix B, *Scope of Accreditation*.

4.1.4 Potential Conflicts of Interest

The laboratory reports to the Senior Vice-President in charge of Operations. This ensures the independence of the laboratory from the rest of the organization. Potential conflicts and/or adverse influences against the laboratory's ability to operate in an independent manner are reduced by random independent checks and/or scheduled internal audits conducted by the Quality Manager and/or his/her appointed representative(s).

The responsibilities of the Senior Vice-President, Operations include:

- developing, managing, and guiding the larger organizations policies and procedures
- serve as a member of the executive committee which organizes and administers the relationship between the organization and the laboratory
- providing focus and coordinating functions regarding technical capabilities, resource acquisition / distribution, quality of services, technician competence, and overall

customer satisfaction
- participates in all senior-level administrative functions/committees of the organization as appointed by the President / CEO

4.1.5 Organization

A) Management and Technical Personnel

Policy:
The laboratory managerial and technical personnel have the necessary authority and resources needed to meet the mandates assigned to their areas.

Details:
Responsibilities are detailed in 4.1.4 (F).

Departures from the organizational and management policies in this manual can only be approved by the President / CEO.

Departures from quality system procedures can only be approved by the Quality Manager.

Departures from test methods or technical standard operating procedures (SOPs) can only be approved by the Senior Vice-President, Operations in his role as the Corporate Metrologist and Technical Manager.

See also section 5.2.

B) Undue Pressure

Policy:
Management and personnel are to be free from any undue internal and external commercial, financial and other pressures that may adversely affect the quality of their work. The integrity of test results is the responsibility of all personnel. Management ensures that employees are never instructed or forced to alter or falsify data.

Details:
The following list provides some guidelines on how employees avoid conflict of interest situations. Employees shall not:
- falsify records, prepare fraudulent reports, or make false claims
- seek or use privileged or confidential company information, or data from any client, for any purpose beyond the scope of employment
- conduct non-laboratory business on laboratory time, or use company facilities or equipment to conduct outside interests in business, unless prior approval has been obtained
- solicit business on their own behalf (rather than the laboratory) from a client
- be employed by, or affiliated with, organizations whose products or services compete with laboratory products or services
- have employment that negatively affects or interferes with their performance of laboratory duties
- compete with the laboratory in the purchase, sale, or leasing of property or goods
- allow association, family, or friends to influence business decisions to their benefit - decisions must be made on a strictly business basis, always in the best interest of the laboratory
- make any decision that provides gains or benefits to the employee and/or others
- have personal financial dealings with an individual or company that does business with the laboratory which might influence decisions made on the laboratory's behalf

Firm adherence to this code of values forms the foundation of our credibility. Personnel involved in dishonest activities are subject to a range of disciplinary action including dismissal.

C) Client Confidentiality

Policy:
It is the policy of our laboratory to protect the confidential information and proprietary rights of our client including the electronic storage and transmission of results.

Details and Procedures:
All employees sign an Employee Confidentiality Agreement. The signed agreement is retained in each employee's Human Resources file.

Test results are only released to the client. Release to someone other than the client requires the express permission of the client, except when the situation contravenes Municipal, State and/ or Federal Legislation and the results must be provided to the appropriate agency. The release of test results to anyone other than the client requires the permission of management. Laboratory reports are reviewed for accuracy prior to release.

D) Operational Integrity

Policy:
The laboratory will avoid involvement in any activities that would diminish confidence in its competence, impartiality, judgment, or operational integrity.

Details and Procedures:
To ensure confidence in laboratory operations a formal quality assurance program is implemented. Technical competence is ensured through check sample programs. Impartiality is assessed through audits and approvals. Judgment is ensured through the hiring of qualified personnel and by continuously refining, upgrading and improving his or her skills. Operational integrity is reviewed by management on a regular basis at management review meetings to ensure continued suitability and effectiveness of laboratory policies and procedures. Any problems are acted on immediately through corrective action procedures.

E) Organizational Structure

Policy:
The organization and management structure of the laboratory, and the relationships between management, technical operations, support services, and the quality system is defined through the aid of an organizational char as illustrated in Appendix A, *Micro Merology Inc. Organizational Line & Staff Chart*.
Details:
Senior management keeps the most current organizational chart on file. An organizational chart is available with this manual as a reference record and is considered the official record on the date it is marked.

F) Responsibility and Authority

President / CEO
- develops primary goals, operating plans, policies, and short and long range objectives for the laboratory; implementing these following Board of Director's approval
- directs and coordinates activities to achieve profit and return on capital
- establishes organizational structure and delegating authority to subordinates
- leads the laboratory towards objectives, meets with and advises other executives, and reviewing results of business operations
- determines action plans to meet the needs of stakeholders
- represents organization to major clients, government agencies, shareholders and the public

Senior Vice-President, Operations (Technical Manager)
- is/are knowledgeable of the scope of all processes under their supervision

- provides the necessary resources (personnel, equipment, supplies) for the quality assurance program, in order to ensure confidence in the laboratory's results
- ensures equipment is maintained and calibrated, reporting all deficiencies (e.g., equipment malfunctions) in the appropriate manner
- ensures personnel are trained for the duties they perform - includes substitutes when regular personnel are absent
- maintains current job descriptions
- maintains records and manage all aspects of testing activities

Quality Manager
- ensures that the Quality System is established, implemented and maintained in accordance with the ISO 9001 and ISO 17025 standards
- manages the internal audit program
- coordinates laboratory accreditation activities
- handles the maintenance and distribution of the Quality Manual and associated documents
- maintains a master list of current versions of quality documentation
- trains personnel on Quality System activities
- monitors the Quality System
- reports on the performance of the Quality System to senior management for review and as a basis for improvement of the Quality System
- supervises the laboratory's inter-laboratory proficiency testing program

Supervisors
- responds to client inquiries and providing professional advice
- hiring personnel
- orientates new personnel
- determines technical training needs of personnel
- conducts employee performance reviews
- scheduling vacation and coverage
- ensures that all health and safety regulations are followed
- ensures that all Human Rights Legislation are complied with
- oversees quality, standard pricing, customized quotations, and invoicing for tests performed
- prioritizes workload
- facilitates operational concerns in their area
- ensures accurate and consistent testing procedures through the validation of all current procedures and by developing, validating and implementing new procedures
- coordinates purchasing requests
- ensures that the operational needs are within budget and advising management of any discrepancies

Scientists and Technicians
- maintains records of all quality activities as documented in SOPs and test methods
- handles samples and performing analyses according to SOPs and test methods
- writes SOPs and test methods
- signs reports when designated with signing authority
- maintains and calibrating equipment
- reports deficiencies or malfunction to the supervisor
- identifies and recording nonconformances on *Corrective Action Requests*
- identifies and recording potential nonconformances on *Preventive Action Requests*
- corrects nonconformances and potential nonconformances
- improves laboratory and/or quality activities on a continuous basis

Research Scientist
- provides vision and direction for research activities
- develops and reviews research proposals

- ensures adequate training is completed for research personnel
- monitors the progress of research projects
- reviews research reports for clients or publication
- ensures quality policies and procedures are followed
- controls the flow of communication between the client and the laboratory

Client Representatives and Administrative Personnel
- performs work functions and keeping records as per approved SOPs and/or laboratory policies
- writes SOPs
- identifies and records nonconformances on *Corrective Action Requests*
- identifies and records potential nonconformances on *Preventive Action Requests*
- corrects nonconformances and potential nonconformances
- improves laboratory and/or quality activities on a continuous basis

G) Laboratory Supervision

Policy:
Adequate supervision is provided in each area of the laboratory for all testing and calibration personnel, including trainees, by persons familiar with the methods and procedures.

Details:
Adequate supervision is ensured through designated supervisors as well as through documentation such as this Quality Manual, test methods and SOPs. A thorough orientation and training program is adhered to for all new employees. Ongoing training for regular personnel is required.

H) Technical Management

Policy:
A technical manager is tasked with the overall responsibility for the technical operations and the provision of resources needed to ensure the required quality of laboratory operations.

Details:
While the technical manager may at times delegate duties to other personnel, the technical manager is accountable for any nonconforming activities.

I) Quality Manager

Policy:
The Quality Manager is appointed by the highest level of management. The Quality Manager, who, irrespective of other duties and responsibilities, has defined responsibility and authority for ensuring that the quality system is implemented and followed. The Quality Manager has direct access to the highest level of management where decisions are taken on laboratory policy or resources.

Details:
This statement notifies all laboratory personnel that **Greg Ganner** is the Quality Manager as authorized below by the President / CEO. Any change in this position requires the reissue of this section to all holders of controlled copies of the Quality Manual. The following signature also serves as approval for this Quality Manual and affirms senior management's commitment to the policies and procedures set forth in this manual.

Allen Ganner
President / CEO

J) Managerial Substitutions

Policy:
Deputies for key personnel are appointed to fulfill the key personnel's duties in their absence.

Details:
In the absence of the Quality Manager, the President / CEO will assume his/her responsibilities.

In the absence of the Technical Manager, the Quality Manager will assume his/her responsibilities.

Management is responsible for ensuring that current and/or increased workload requirements are met. This includes making adjustments as a result of employee absence. Only fully trained employees are utilized to fulfill the duties of personnel who are absent.
If sufficient human resources are not available, management will identify the best possible solution to meet operational requirements.

Revision History

Revision 0

4.2 Quality System

The Ten Second Tutorial

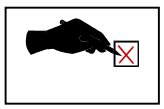
This section tells you that our Quality System is based on the premises:

1. Define your policy on quality
2. Say what you do (through documentation)
3. Do what you say (following your documentation)
4. Record what you did

Key Words

Establish, Implement, and Maintain
Policies, Systems, Processes, Programs, Procedures, Instructions
Communicate, Understand
Quality Policy Statement
Quality Manual
SOP
Test Method

Cross-references



ISO 17025:1999 Section 4.2

ISO 9001:2000 Section 4.1, 4.2.1, 4.2.2, 5.1, 5.4.1, 5.4.2, 5.5.1, 6.2.1, 7.1

4.2.1 Policies and Procedures

Policy:
The Quality System is established, implemented, and maintained by management. It is applicable to all the fields of testing and activities in which the laboratory is involved and undertakes. All policies, systems, programs, procedures and instructions are documented to the extent necessary to enable the laboratory to assure the quality of results generated. These documents are communicated to, understood by, available to, and implemented by the appropriate personnel.

Details:
The purpose of our Quality System is to ensure that all services and products satisfy the client's requirements and have been designed, manufactured, and delivered under controlled conditions.

The effectiveness of the Quality System is assessed in several ways:

- by a program of planned internal audits, covering all aspects of the operation of the quality system
- by regular management reviews of the suitability and effectiveness of the quality system
- by analysis of potential and actual problems as shown by client complaints and supplier and subcontractor assessments
- by other methods approved from time to time by the <Click here and type appropriate TITLE>

This Quality Manual and associated documents (including procedures) and records serves as the quality plan for the laboratory. Other documents and records include:

- standard operating procedures
- quality control plans in test methods
- organizational charts
- proposals
- project management schemes

4.2.2 Quality Policy Statement

Policy:
The policies and objectives for laboratory operations are documented in this Quality Manual. The overall objectives are set out in the Quality Policy Statement. The Quality Policy Statement is issued under the authority of the {President/Director/CEO/General Manager} on the effective date.

Quality Policy Statement:
To ensure accurate and timely *{type of testing - analytical, research, interpretive, [calibration], technical}* services and to continuously meet or exceed the stated or implied expectations of our clients through day-to-day interactions.

Effective Date: <Click here and type EFFECTIVE DATE - YYYY/MM/DD>

a) *Management commitment to good professional practice and quality of services provided to the client*:
Tests and calibrations are always carried out in accordance with stated standardized methods and clients' requirements. Requests to perform tests that may jeopardize an objective result or have a low validity are rejected.

b) *Standards of service include*:
- Client Satisfaction
- Accurate
- Timely

Excellence in the workplace is promoted by providing all employees with the knowledge, training, and tools necessary to allow for the completion of accurate and timely work.

c) *Purpose*: to manage our business by meeting the needs of our clients.

d) *Personnel*: familiarize themselves with quality documentation and implement the policies and procedures in their work.

e) *Management is committed to complying with ISO 17025 and ISO 9001 international standards*: the objective of this Quality Manual is to document the compliant policies and associated procedures that are integrated into our daily activities.

Additional objectives include:

- to establish the level of the laboratory's performance
- to make test method changes to improve performance
- to participate in proficiency testing or quality evaluation programs with peer laboratories
- to ensure that all personnel are trained to a level of familiarity with the quality system appropriate to the individual's degree of responsibility
- to improve and validate laboratory methodologies by participation in method validation collaborative tests
- to establish and report on quality savings

4.2.3 Quality Manual

Policy:
This Quality Manual outlines the structure of the documentation used in the quality system. This Quality Manual makes reference to supporting procedures including technical procedures and is maintained up to date.

Details:
This quality system is structured in three tiers of documentation. The tiers are as follows
I. Quality Manual
II. Standard Operating Procedures and Test Methods
III. Records

For most clients, this Quality Manual and the associated documents form a general Quality Plan. If necessary, specific Quality Plans will be prepared on a 'per-client' basis. These Quality Plans will modify the general requirements stated in the Manual and associated documents.

All of the above documents are controlled documents.

The following records and directive documents are referenced in the Quality Manual, but maintained separately:

- organizational chart (section 4.1.5.E)
- copies of the Quality Policy Statement posted in the laboratory (section 4.2.2)
- identification of resources and management review (section 4.14.1)
- job descriptions (section 5.2.4)
- statistical techniques (section 5.9)
- test reports (section 4.12.2)
- identification of the laboratory's approved signatures (section 5.10.2)
- laboratory's scope of tests (section 4.1.3)
- equipment inventory and records (sections 5.5.4 and 5.5.5)
- calibration status indicators (section 5.5.8)
- reference standards inventory (section 5.6.3)
- verification records (section 5.9)
- quality control plan / criteria for workmanship (section 5.4.1)
- corrective action records (section 4.10)

- preventive action records (section 4.11)
- client complaint records (section 4.8.1)
- audit schedule and records (section 4.13.3)
- procurement and subcontracting records (sections 4.6 and 4.5.4)
- training records (section 5.2.5)
- master list of documentation (section 4.3.2)
- confidentiality agreements (section 4.1.5 C)
- contract review (section 4.4.2)
- validation of test methods (section 5.4.5)
- facility floor plan (section 5.3.1)

4.2.4 Technical Management and the Quality Manager

The roles and responsibilities for technical management and the Quality Manager are outlined in section 4.1.4 (F) of this manual.

Technical management ensures that section 5 of this manual is implemented and maintained. The Quality Manager ensures that section 4 of this manual is implemented and maintained.

Revision History

Revision 0

4.3 Document Control

The Ten Second Tutorial

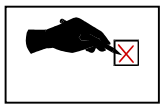
This section tells you that Document Control involves:

1. Writing good procedures
2. Getting them to the users
3. Keeping procedures good

Key Words

Controlled Document
Master List
Unique Identification
Revise
Revision Number
Effective Date
Review and Approval
Obsolete
Archive
Hand-written changes

Cross-references



ISO 17025:1999 Section 4.3

ISO 9001:2000 Section 4.2.1, 4.2.3

4.3.1 Policies and Procedures

Policy:
The SOP# QSP 4-3-1 is used to control all quality system documents (internally generated and from external sources). These include documents of external origin, such as regulations, standards, other normative documents, test and/or calibration methods, as well as drawings, specifications, instructions, and manuals.

Details:
Document means any information or instructions including policy statements, procedures, specifications, calibration tables, charts, text books, posters, notices, memoranda, software, drawings, and plans. These may be in various media, whether hard copy or electronic and they may be digital, analog, photographic or written.

The documents to be controlled include:
- Quality Manual
- Standard Operating Procedures and test methods
- Forms
- Standards

The control of data related to testing and calibration is covered in section 5.4.7. The control of records is covered in section 4.12.

4.3.2 Document Approval and Issue

4.3.2.1 Review / Approval / Master List

Policy and Details:
All documents issued to personnel in the laboratory as part of the quality system are reviewed and approved for use by authorized personnel prior to issue (i.e., reviewed by personnel knowledgeable in the documented activity and then approved by management). A master list identifying the current revision status and distribution of documents in the quality system is readily available in order to preclude the use of invalid and/or obsolete documents (see SOP# QSP 4-3-1). A revision history of documents is also maintained. Documents are formally reviewed on a biennial basis to ensure their continuing suitability.

4.3.2.2 Availability and Obsolete Documents

Policy and Details:
The master list shows the current status of all controlled documents. The master list document is organized with the following information:
- Document #
- Title
- Revision #
- Date of issue
- Date of last review
- Locations

Controlled documents are approved before issue.

The SOP# QSP 4-3-1 for document control ensures that:
- authorized editions of appropriate documents are available at all locations where operations essential to the effective functioning of the laboratory are performed
- documents are periodically reviewed and where necessary revised to ensure continuing suitability and compliance with applicable requirements

- invalid or obsolete documents are promptly removed from all points of issue or use to assure against unintended use
- obsolete documents retained for either legal or knowledge preservation purposes are suitably marked (i.e., stamped "OBSOLETE" and dated)

4.3.2.3 Identification

Policy and Details:
All quality system documentation is identified by:

- date of issue and/or revision number
- page numbering
- total number of pages (e.g., page 5 of 5)
- issuing authority (i.e., approval signature)

4.3.3 Document Changes

4.3.3.1 Review / Approval

Policy:
Changes to documents are reviewed and approved by the same function (i.e., personnel or position) that performed the original review [unless specifically designated otherwise]. [The designated personnel have access to pertinent background information upon which to base their review and approval].

Details:
Developments in policies and procedures require documents to be changed from time to time. Changes to documents receive the same level of review and approval as the originals.

The Quality Manual is reviewed annually by the Quality Manager. Records are kept of this review.

Test methods and SOPs are reviewed on a biennial basis. Procedures for this are outlined in SOP# QSP 4-3-1.

Obsolete documents are withdrawn, but are retained for archive purposes and clearly labeled as obsolete.

4.3.3.2 Identification of Changes

Policy:
The nature of document changes is identified in the document.

Details:
As outlined in SOP# QSP 4-3-1.

In general, the nature of changes is identified in the document with a vertical bar in the left-hand margin. Revision history is recorded at the end of the document.

4.3.3.3 Amendments by Hand

Policy and Details:
[Option 1]
{Hand-written amendments to documents are not permitted}

[Option 2]

{Hand-written amendments to documents are permitted only by those personnel authorized to do so (see section 4.1.5 A). Amendments are clearly marked, initialed, and dated. A revised document is formally re-issued at the time of the biennial review. For further details refer to SOP# QSP 4-3-1}.

4.3.3.4 Computerized Documents

Policy and Details:
The SOP# QSP 4-3-1 details how changes in documents maintained in computerized systems are made and controlled.

Revision History

Revision 0

4.4 Review of Requests, Tenders, and Contracts

The Ten Second Tutorial

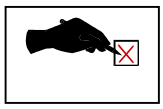
This section tells you that you must:

1. Clearly understand client requirements

Key Words

Requirements
Subcontractor
Request
Tender
Contract
Review

Cross-references



ISO 17025:1999 Section 4.4

ISO 9001:2000 Section 5.2, 7.2.1, 7.2.2, 7.2.3

4.4.1 Policies and Procedures

Policy:
The SOP# QSP 4-4-1 is used to review requests, tenders, or contracts. This procedure ensures that:
a) the client requirements including the methods to be used are adequately defined, documented and understood (see section 5.4.2)
b) the laboratory has the capability and resources to meet the requirements
c) the appropriate test [and/or calibration] method is selected and capable of meeting the client's requirements (see section 5.4.2)

Any differences between the request or tender and the contract are resolved before any work commences. Each contract must be acceptable by both the laboratory and the client.

Details:
The request, tender and contract review is conducted in a practical and efficient manner, and the effect of financial, legal, and time schedule aspects are taken into account. [Internal client review of requests, tenders, and contracts are performed in a simplified manner.]

The review of capability establishes that the laboratory possesses the necessary physical, personnel, and information resources, and that the laboratory's personnel have the skills and expertise necessary for the performance of the tests [and/or calibrations] in question. The review may also encompass results of earlier participation in inter-laboratory comparisons or proficiency testing and/or the running of trial test [or calibration programs] using samples or items of known value in order to determine uncertainties of measurement, limits of detection, and confidence limits.

The contract review ensures that each client's requirements are adequately defined and documented before the service or product is ordered or dispatched. This should ensure that any order, once accepted, can be completed without delay, and that the client's requirements including delivery date, technical specification, and cost can be met.

If the contract review highlights any ambiguities or uncertainties then the client will be contacted and the problem resolved before the order is accepted.

The SOP# QSP 4-4-1 also describes the activities that take place should there be a subsequent amendment to a client's order.
Typical types of contracts include:

- approved service quotations
- confidentiality agreements
- non-disclosure agreements
- sample submission requests
- memorandum of agreement
- memorandum of understanding
- research proposals and contracts
- verbal orders (oral agreements)
- activity plans

4.4.2 Records of Review

Policy:
Records of request, tender and contract review, including significant changes, are maintained. Records of pertinent discussions with a client relating to the client's requirements or the work during the period of execution of the contract are also maintained.

Details:
For review of routine and other simple tasks, the date and the identification (e.g., initials) of the person in the laboratory responsible for carrying out the contracted work are considered adequate. For repetitive routine tasks, the review need be made only at the initial enquiry stage or on grant of the contract for on-going routine work performed under a general agreement with the client, provided that the client's requirements remain unchanged. For new, complex or advanced testing [and/or calibration] tasks, a more comprehensive record is maintained.

4.4.3 Review of Subcontracted Work

Policy:
Request, tender, and contract review also includes work that is subcontracted by the laboratory.

Details:
Subcontractor laboratories are reviewed as described in section 4.5.

4.4.4 Notification of Client

Policy and Details:
Clients are informed of deviations from the contract. This is typically communicated to the client prior to the performing the deviation.

4.4.5 Contract Amendment

Policy and Details:
If a contract needs to be amended after the work has commenced, the same contract review process is repeated and any amendments are communicated to all affected personnel.

Revision History

Revision 0

4.5 Subcontracting of Tests and Calibrations

The Ten Second Tutorial

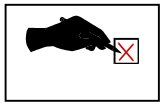
This section tells you that we must:

1. Know what tests and calibrations need to be done by another laboratory
2. Check out the other laboratories

Key Words

Competence
Register of Subcontractors
Assessment

Cross-references



ISO 17025:1999 Section 4.5

ISO 9001:2000 Section 7.4.1, 7.4.3, 8.2.4

4.5.1 Subcontractor Competence

Policy:
Work that must be subcontracted due to:
- unforeseen circumstances
- workload
- large contracts
- contracts requiring some extra technical expertise

is subcontracted to a technically competent laboratory.

Details:
The subcontracted laboratory demonstrates technical competence by possession or receipt of one or more of the following:
- recognized technical accreditation
- registration under the ISO 9001 standard
- satisfactory performance of appropriate quality control check samples (certified reference material, in-house reference material or replicate analysis
- audit of the subcontractor's quality system by our auditors

It is the responsibility of the Quality Manager to assess and approve the competence level of subcontractor laboratories.

4.5.2 Client Approval

Policy:
Clients are advised of work (or any portion thereof) that is being subcontracted to another laboratory and their approval is obtained (preferably in writing).

Details:
Clients are advised of subcontracted work through fee schedules or any type of contract listed in section 4.4.1.

4.5.3 Assurance of Subcontractor Competence

Policy:
The laboratory is responsible to the client for the subcontractor's work. Technical competence of subcontractor laboratories is demonstrated through various records.

> **Note** – there may be circumstances where the client specifies which subcontractor is to be used. In such cases we may not be able to demonstrate the competence of the subcontractor and therefore are not responsible for the results.

Details:
Records of subcontractor competence include, but are not limited to, the following:
- accreditation certificates or documentation
- registration certificates
- check sample results
- audit results
- approval by the Quality Manager

4.5.4 Subcontractor Register

Policy:
A register of all subcontractors performing tests and calibrations is maintained.

Details:
The approved register of subcontractors and all assessment records are maintained by the Quality Manager.

Revision History

Revision 0

4.6 Purchasing Services and Supplies

The Ten Second Tutorial

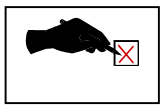
This section tells you that we must:

1. Know what we want
2. Check out our suppliers

Key Words

Selection
Verify
Specifications
History

Cross-references



ISO 17025:1999 Section 4.6

ISO 9001:2000 Section 7.4, 8.2.4

4.6.1 Policies and Procedures

Policy:
The SOP# QSP 4-6-1 is used to select and purchase services and supplies. The SOP# QSP 4-6-1 is used for procurement, reception, and storage of supplies.

Details:
Consumable materials are stored according to the appropriate test method, SOP, or work instruction.

4.6.2 Specifications

Policy:
Only services and supplies of the required quality are used. These quality requirements are detailed in laboratory SOPs under the "*Materials Required"* section and will identify the appropriate minimum specifications when necessary.

Details:
Packing slips are checked against package content labels and matched with the *{Request for Purchase / Purchase Order}* if accepted. Once accepted, the packing slip is dated and initialed as evidence of compliance. Certificates of analysis (COA) are maintained on file after the COA is checked to ensure the received item meets minimum specifications.

Chemicals are purchased with manufacturer's certificates where possible. Uncertified chemicals are purchased from ISO 9000 registered companies. Whatever the source, the laboratory verifies the quality of the standards by comparing the new batch of standards to the old. Due regard is paid to the manufacturer's recommendations on storage and shelf life.

Reagents are generally purchased from manufacturers who have a quality system based on ISO 9000. The grade of any reagent used (including water) is stated in the method together with guidance on any particular precautions to be observed in its preparation or use.

Where no independent assurance of the quality of procured goods or services is available or the supplier's evidence is insufficient the laboratory ensures that purchased goods and services comply with specified requirements. Where possible and practical the laboratory ensures that goods are inspected, calibrated, or are otherwise in compliance with any standard specification relevant to the calibrations or tests concerned.

4.6.3 Purchasing Documents

Policy:
Purchasing requests are recorded on the *{Request for Purchase / Purchase Order}* form and contain data describing the product ordered. The *{Request for Purchase / Purchase Order}* is reviewed and approved for technical content prior to release.

Details:
The description may include type, class, grade, precise identification, specifications, drawings, inspection instructions, other technical data including approval of test results, quality required and quality system standard under which they were produced.

The completion of the *{Request for Purchase / Purchase Order}* is the responsibility of the {originator / supervisor}. They review the *{Request for Purchase / Purchase Order}* for accuracy and approve the technical content prior to release with their signature and the date.

4.6.4 Approved Suppliers

Policy:
Suppliers of critical services are evaluated and approved before use. An approved supplier list is maintained.

Details:
Audits or tender evaluation is conducted to qualify suppliers of critical services prior to use. The criteria for evaluation may include, but is not limited to the following:

- references
- accreditation
- formal recognition

The records are maintained by purchasing personnel.

Revision History

Revision 0

4.7 Service to the Client

The Ten Second Tutorial

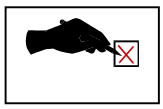
This section tells you that we must:

1. Facilitate clarification of the client's request
2. Give client access to relevant testing area
3. Maintain client contact
4. Inform client of delays or deviations
5. Utilize client surveys

Key Words

Clarification
Deviations
Delays
Client Satisfaction Survey

Cross-references



ISO 17025:1999 Section 4.7

ISO 9001:2000 Section 7.2.1, 7.2.3, 7.4.3, 7.5.1

4.7.1 Policies and Procedures

Policy:
Client requests are clarified for the clients or their representatives. Furthermore the client or their representative will be afforded the right to monitor the performance of the laboratory in relation to the work performed.

Details and Procedures:
Service to the client includes:

- Affording the client or the client's representative reasonable access to relevant areas of the laboratory for the witnessing of work performed for the client; it is understood that such access should not conflict with rules of confidentiality of work for other clients or with safety.

- Preparing, packaging, and dispatching of test [and calibration] items needed by the client for verification purposes.

- Maintaining of open contacts. The client values advice and guidance in technical matters, and opinions and interpretations based on results. Contact with the client, especially in large assignments, should be maintained throughout the work. The laboratory should inform the client of any delays or major deviations in the performance of the tests [and calibrations].

- Obtaining feedback from the client. Positive and negative feedback can be obtained passively through ongoing communications with the client or actively through client satisfaction surveys. The feedback is used to improve the quality system, testing [and calibration] activities, and client service.

Revision History

Revision 0

4.8 Complaints

The Ten Second Tutorial

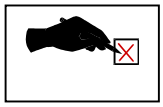
This section tells you that you must:

1. Maintain records of Complaints
2. Maintain records of Corrective Action

Key Words

Resolving
Investigation
Corrective Action
Follow-up Verification

Cross-references



ISO 17025:1999 Section 4.8

ISO 9001:2000 Section 7.2.3

4.8.1 Policies and Procedures

Policy:
The SOP# QSP 4-8-1 is used for resolving complaints received from clients or other parties. Records are maintained of all complaints and follow-up.

Details:
Records of complaints include the following information:

- details of the complaint
- investigation
- corrective action
- follow-up verification

See also section 4.10.

All personnel are responsible for recording and responding to complaints.

Revision History

Revision 0

4.9 Control of Nonconforming Testing and Calibration Work

The Ten Second Tutorial

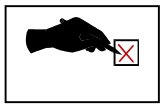
This section tells you that you must:

1. Stop testing when nonconforming work is identified
2. Figure out what is causing nonconforming work

Key Words

Nonconforming
Root Cause

Cross-references



ISO 17025:1999 Section 4.9

ISO 9001:2000 Section 5.5.1, 7.4.3, 7.5.1, 8.2.4, 8.3

4.9.1 Procedures to Control Nonconforming Work

Policy:
The SOP# QSP 4-9-1 is used to control any aspect of testing and/or calibration work, or the results of this work, when they do not conform with the test methods or the agreed requirements of the client.

Details:
The procedure ensures that:

- Responsibilities and authorities for the management of nonconforming work are designated and actions (including halting of work and withholding of test reports [and calibration certificates] as necessary) are defined and taken into consideration when nonconforming work is identified
- an evaluation of the significance of the nonconforming work is made
- remedial actions are taken immediately, together with any decision about the acceptability of the nonconforming work
- where necessary, the client is notified and the work is recalled
- the responsibility for authorizing the resumption of work is defined

Identification of nonconforming work or problems with the quality system or with testing [and/or calibration] activities can occur at various locations within the quality system and technical operations such as:

- client complaints
- quality control
- instrument calibration
- checking of consumable materials
- staff observations or supervision
- test report [and calibration certificate] checking
- management reviews
- internal or external audits

4.9.2 Root Cause Analysis

Policy:
Where evaluation indicates that nonconforming work could recur or that there is doubt about the compliance of the laboratory's operations with its own policies and procedures, the corrective action procedures given in 4.10 are followed to identify the root cause(s) of the problem and to eliminate this (these) cause(s).

Details:
The SOP# QSP 4-10-1 outlines recording the root cause analysis for investigating nonconforming work.

Situations warranting corrective action investigation include:
- failure to comply with test method including all applicable procedures necessary to ensure the integrity and representative nature of the sample
- presentation of uncertain knowledge as to compliance with test methods including all applicable procedures necessary to ensure the integrity and representative nature of the sample
- failure or suspected failure in method performance as demonstrated by results provided by quality control samples
- lack of relevant evidence provided by quality audit, proficiency testing, or client feedback
- lack of relevant evidence provided by data validation
- neglect to check the inherent property of the sample that compromises the testing

Revision History

Revision 0

4.10 Corrective Action

The Ten Second Tutorial

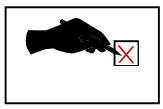
This section tells you that you must:

1. Identify problems
2. Determine why the problem occurred
3. Fix the cause of the problem
4. Verify that your changes worked

Key Words

CAR
Root Cause
Monitor
Audit
Nonconforming work

Cross-references



ISO 17025:1999 Section 4.10

ISO 9001:2000 Section 5.5.1, 8.1, 8.2.2, 8.2.3, 8.4, 8.5.2, 8.5.3

4.10.1 General

Policy:
The SOP# QSP 4-10-1 is utilized for implementing corrective action when nonconforming work or departures from policies and procedures in the quality system or technical operations have been identified. The procedure requires that appropriate authority be designated for the implementation of corrective actions. The procedure includes cause analysis, selection and implementation of corrective action, and monitoring of actions.

Details:
Problems with the quality system or technical operations of the laboratory may be identified through a variety of activities, such as control of nonconforming work, internal or external audits, management reviews, feed-back from clients, or staff observations.

Corrective action investigations are documented and required changes to operational procedures are implemented. The corrective action request (CAR), investigation and resolution are recorded on a CAR form.

4.10.2 Cause Analysis

Policy:
Corrective action always begins with an investigation to determine root cause(s) of the problem (see SOP# QSP 4-10-1).

Details:
Potential causes of the problem could include client requirements, the samples, sample specifications, methods and procedures, personnel skills and training, consumable materials, or equipment and its calibration.

4.10.3 Selection and Implementation of Corrective Actions

Policy and Details:
After determining the cause(s) of the problem, potential corrective actions are identified. The most likely action(s) (this includes practical and/or reasonable) are selected and implemented to eliminate the problem and to prevent recurrence. It should be noted that any corrective actions taken to eliminate the cause(s) of nonconformances or other departures are to an appropriate degree to address the magnitude of the problem and commensurate with the risks encountered (Note – in plain language, this means determine whether the benefit outweighs the cost). Controls are applied to prevent recurrence. The laboratory documents and implements the required changes resulting from corrective action investigations.

4.10.4 Monitoring of Corrective Action

Policy:
After implementing the corrective action(s), the laboratory monitors the results to ensure that the actions taken have been effective in overcoming the problems originally identified.

Details:
Monitoring is assigned to an appropriate individual such as the originator of the CAR or the originator's manager. Changes resulting from corrective action are documented.

4.10.5 Additional Audits

Policy:
Where the identification of nonconformances or departures casts doubts on compliance of policies, procedures, regulations, international quality standards, the appropriate areas of activity are promptly audited in accordance with section 4.13.

Details:
Special audits follow the implementation of corrective actions to confirm their effectiveness. A special audit is only necessary when a serious issue or risk to the business is identified. Special audits are carried out by trained and qualified personnel who are [whenever resources permit] independent of the activity to be audited. See section 4.13 for more details.

Revision History

Revision 0

4.11 Preventive Action

The Ten Second Tutorial

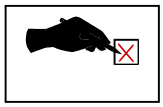
This section tells you that you must:

1. Identify potential problems
2. Determine why the problem could occur
3. Fix the cause of the potential problem
4. Verify that your changes worked

Key Words

PAR
Potential Nonconformance
Action Plan

Cross-references



ISO 17025:1999 Section 4.11

ISO 9001:2000 Section 8.4, 8.5.2, 8.5.3

4.11.1 Preventive Action Identification

Policy:
Opportunities for needed improvement and potential sources of nonconformances, either technical or with the quality system shall be identified. If action is required, action plans are developed, implemented and monitored, to reduce the likelihood of occurrence of such nonconformances and to take advantage of the improvement opportunities.

Details:

Records of preventive action include the following information:

- details of potential nonconformances
- investigation
- preventive action
- follow-up verification

These records are maintained in the [Preventive Action Request (PAR) form/binder].

4.11.2 Preventive Action Plans

Policy:
The preventive action procedure includes the initiation of such actions and application of controls to ensure that they are effective.

Details:
Preventive action may result from the review of operational procedures and analysis of data. Analysis of data includes trend analysis, analysis of proficiency testing results, and risk analysis.

The SOP# QSP 4-11-1 is utilized to implement opportunities for needed improvement and prevent potential sources of nonconformances.

Revision History

Revision 0

4.12 Control of Records

The Ten Second Tutorial

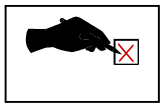
This section tells you that you must:

1. Identify the records to be kept
2. Keep identified records in a useful state
3. Destroy records when they are no longer needed

Key Words

Collection
Indexing
Access
Storage
Maintenance
Disposition
Legible
Traceable
Retrievable
Secure

Cross-references



ISO 17025:1999 Section 4.12

ISO 9001:2000 Section 4.2.4, 6.3, 6.4, 7.1, 7.5.1, 7.5.2, 7.5.3, 8.1, 8.2.2, 8.2.3, 8.2.4

4.12.1 General

4.12.1.1 Procedures

Policy:
The SOP# QSP 4-12-1 is used to identify, collect, index, access, file, store, maintain, protect, backup, and dispose quality and technical records. Quality records include reports from internal audits and management reviews as well as corrective and preventive action records.

Details:
Records are available to demonstrate conformance to requirements and effective operation of the Quality System. Quality records from suppliers are also controlled.

All records, including test reports, are safely stored and held secure in locked areas, and in confidence to the client. Records are maintained in the designated archival area for <Click here and type appropriate NUMBER OF YEARS> years.

The master list of records is organized with the following information:
- Record No. / Form No.
- Record Name
- Filing Method (loose forms filed monthly, quarterly, semi-annual, annual or electronic)
- Active Files (files referred to within the work area) / Retention Period / Location
- Inactive Files (files referred to but not often and kept in storage) / Retention Period / Location
- Persons / Positions Responsible / Users

The dating format for records is [YYYY/MM/DD].

4.12.1.2 Record Integrity

Policy:
All records are to be legible and shall be retained in such a way that they are readily retrievable in facilities that provide a suitable environment to prevent damage or deterioration and to prevent loss.

Details:
The retention times for records are generally set at <Click here and type appropriate NUMBER OF YEARS> years. Exceptions to this are [list your exceptions].

Records may be in the form of any type of media, such as hard copy or electronic media.

4.12.1.3 Record Security

Policy:
All records are held secure and in confidence.

Details:
Access to records is secured through locked rooms and filing cabinets.

4.12.1.4 Record Backup

Policy:
The SOP# QSP 4-12-1 is followed to protect and backup data/records held on computers at all times and to prevent unauthorized access to or amendment of data/records on computers.

Details:
Data is password protected.

Backups ensure integrity and availability of data / information in the event of a system / power failure.

4.12.2 Technical Records

4.12.2.1 Record Information

Policy:
Original observations, calculations, derived data and sufficient information to establish an audit trail, calibration records, personnel records and a copy of each test report [or calibration certificate] issued are retained for <Click here and type appropriate NUMBER OF YEARS> years.

The records for each test or calibration shall contain sufficient information to facilitate, if possible, identification of factors affecting the test uncertainty and to enable the test or calibration to be repeated under conditions as close as possible to the original. The records include the identity of personnel responsible for sampling, performing of each test and/or calibration and checking of results.

Details:
Technical records are accumulations of data (see 5.4.7) and information that result from carrying out tests and/or calibrations and which indicate whether specified quality or process parameters are achieved. They may include forms, contracts, work sheets, work books, note books, instrument printouts, magnetic media, check sheets, work notes, control graphs, test reports, calibration certificates, client's notes, papers and feedback, and test reports [and calibration certificates] to clients.

The records for each test contain sufficient information to permit its repetition. Records include:
- date of sampling
- sample receipt
- sample handling, storage, and disposal
- identification of personnel
- analyst proficiency
- equipment identification and performance
- calibration records
- media performance, where appropriate
- test organism batch # or lot #, where appropriate
- results
- reports (mailed, faxed)
- review

Note – the above records may be stored in separate locations. They are cross-referenced for easy retrieval.

4.12.2.2 Recording

Policy:
Observations, data, and calculations are clearly and permanently recorded and identifiable to the specific job at the time they are made.

Details:
Handwritten records must be legible and made with indelible ink immediately after an observation, after data is collected and/or after calculations are made.

4.12.2.3 Corrections to Records

Policy:
Changes to test data are made so as not to obscure or delete the previous data entry.

Details:
Mistakes are crossed out and the correct value entered alongside. Mistakes are not erased, made illegible, or deleted. All alterations to records are signed or initialed by the person making the correction. In the case of computer-collected data, similar measures are taken to avoid loss or change of original data.

Revision History

Revision 0

4.13 Internal Audits

The Ten Second Tutorial

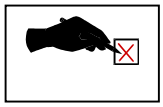
This section tells you that:

1. Trained internal auditors examine your internal operations for quality
2. Auditors report the results to those in charge
3. You must correct any areas that need fixing

Key Words

Schedule
Elements
Independent
Nonconformance
CAR

Cross-references



ISO 17025:1999 Section 4.13

ISO 9001:2000 Section 8.1, 8.2.2, 8.2.3

4.13.1 Internal Audit Program

Policy:
The internal audit program involves periodic audits conducted according to a predetermined schedule for each year. This program is defined on an annual basis and conducted as outlined in this section with further details found in SOP# QSP 4-13-1. All elements of this Quality Manual will be audited each year and all relevant laboratory records are available to personnel conducting the audit. These audits are performed to verify operations continue to comply with the requirements of this Quality Manual and are effective.

Details:
The Quality Manual, test procedures, and laboratory results are verified for compliance. It is the responsibility of the Quality Manager to plan and organize audits as required by the schedule and requested by management. Audits are carried out by trained and qualified personnel who are [wherever resources permit] independent of the activity to be audited. Personnel are not to audit their own activities except when it can be demonstrated that an effective audit will be carried out (see also 4.10.5). Audits are performed through the aid of a checklist prepared in advance to minimize the possibility of overlooking any details during the audit.

Generally, the types of audits include:
- quality management system
- processes and procedures
- products, services, and reports

4.13.2 Corrective Action

Policy:
When audit findings cast doubt on the effectiveness of the operations or on the correctness or validity of test or calibration results, timely corrective action is taken and clients are notified if investigations show that laboratory results may have been affected.

Details:
Nonconformances that can be resolved easily are to be corrected immediately, ideally during the audit. Records are made on the audit checklist. Nonconformances that require a more involved resolution are recorded on a CAR and resolved as described in section 4.10.

Corrective actions and client modifications must be kept on record for each audit deviation that casts doubt as described in this section.

4.13.3 Records and Management

Policy:
Records are made of the activity being audited, the audit findings, and corrective actions that arise. Management ensures that corrective actions are discharged within an appropriate and agreed timeline.

Details:
A report is prepared by the auditors and distributed to those audited and/or the area manager/supervisor within an appropriate and agreed timeline. The audit report may include the following sections, as appropriate:
- audit objective and scope
- area or section audited
- personnel involved – auditors and auditees
- date of audit
- reference documents

- observations including nonconformances and commendations
- opening and closing meetings
- recommendations
- audit report distribution

The appropriate manager is responsible for ensuring that corrective actions are sufficiently recorded. Follow-up is performed by the auditor and recorded when corrective action is complete and deemed effective. The audit records are kept in the laboratory.

4.13.4 Follow-up Audits

Policy:
Follow-up audits are performed to verify and record the implementation and effectiveness of the corrective action taken.

Details:
The follow-up audit is performed at a mutually acceptable time between the area implementing corrective action and the auditor. This time is determined when the CAR is issued.

Revision History

Revision 0

4.14 Management Reviews

The Ten Second Tutorial

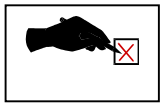
This section tells you that management must:

1. Periodically review technical competence and client satisfaction
2. Keep records of reviews
3. Ensure follow-up is executed
4. Measure progress

Key Words

Supervisor Reports
Audit Reports
CAR / PAR
Proficiency Results
Client Satisfaction Survey
Resources

Cross-references



ISO 17025:1999 Section 4.14

ISO 9001:2000 Section 5.1, 5.4.2, 5.6, 6.2.1, 7.1, 8.5.1

4.14.1 Review of Quality System and Testing

Policy:
Management periodically (at least annually) and in accordance with a predetermined schedule and SOP# QSP 4-14-1, conduct a review of the laboratory's quality system and testing and/or calibration activities to ensure their continuing suitability and effectiveness and to introduce any necessary changes or improvements.

Details:
The review takes account of:

- suitability of policies and procedures
- reports from managerial and supervisory personnel
- the outcome of recent internal audits
- corrective and preventive actions
- assessments by external bodies
- results of inter-laboratory comparisons or proficiency tests
- changes in the volume and type of work undertaken
- feedback from clients, including complaints and client satisfaction surveys
- other relevant factors, such as quality control activities, resources and personnel training

A minimum period for conducting a management review is once a year. Results of the review feed into the laboratory planning system and include goals, objectives and action plans for the coming year.

A management review can be supplemented by consideration of related subjects at regular management meetings.

4.14.2 Findings, Actions, and Records

Policy and Details:
Findings from management reviews and the actions that arise are recorded in the minutes of the meeting. Management will ensure that the actions are discharged within an appropriate and agreed timeline.

Revision History

Revision 0

5.1 General

The Ten Second Tutorial

This section informs you that:

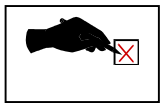
1. Many factors contribute to the correctness and reliability of tests and/or calibrations
2. The laboratory must account for these factors

Key Words

Correctness
Reliability

Uncertainty

Cross-references



ISO 17025:1999 Section 5.1
ISO 9001:1994 Section N/A
ISO 9001:2000 Section N/A

5.1.1 Correctness and Reliability

Policy and Details:
Correctness and reliability of the tests and/or calibrations performed have many contributing factors including:

- human factors (see section 5.2)
- accommodation and environmental conditions (see section 5.3)
- test and calibration methods and method validation (see section 5.4)
- equipment (see section 5.5)
- measurement traceability (see section 5.6)
- sampling (see section 5.7)
- handling of test and calibration items (see section 5.8)

5.1.2 Measurement Uncertainty

Policy:
When developing test and calibration methods and procedures, total measurement uncertainty must be accounted for in the training and qualification of personnel, and in the selection and calibration of equipment.

Details:
The extent to which the factors contribute to total measurement uncertainty differs between (types of) tests and between (types of) calibrations.

See section 5.4.6 for more details.

Revision History

Revision 0

5.2 Personnel

The Ten Second Tutorial

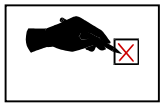
This section tells you that management:

1. Analyzes training needs
2. Provides training to employees for them to do their jobs
3. Qualifies people performing specific tasks

Key Words

Competence
Qualification
Authorize
Training Needs
Job Description
Registry of Skills

Cross-references



ISO 17025:1999 Section 5.2

ISO 9001:2000 Section 5.5.1, 6.2.1, 6.2.2, 7.5.1

5.2.1 Competence and Qualification

Policy:
Management ensures the competency of all specific equipment operators, those performing tests and/or calibrations, those evaluating results and sign test reports and calibration certificates. Appropriate supervision is provided for employees undergoing training. Personnel performing specific tasks are qualified on the basis of appropriate education, training, experience and/or demonstrated skills, as required.

In addition, personnel responsible for the opinions and interpretations included in test reports also have:
- relevant knowledge of the technology used for the manufacturing of the items, materials, products tested, or the way they are used or intended to be used and of the defects or degradation that may occur during or in service
- knowledge of the general requirements expressed in the legislation and standards
- an understanding of the significance of deviations found with regard to the normal use of the items, materials, or products concerned

Details:
Management defines the minimum levels of qualification and experience necessary for all posts within the laboratory. In some technical areas (e.g., fiber optic testing) it may be required that the personnel performing certain tasks be certified. The laboratory is responsible for fulfilling specified certification requirements of personnel. The requirements for personnel certification might be regulatory, might be included in the standards for the specific technical field, or required by the client.

Continued competence is monitored and where this is not achieved, the need to retrain personnel is considered. Where a method or technique is not in regular use, verification of personnel performance before they undertake tests, may be necessary.

5.2.2 Training Policies and Procedures

Policy:
Management will formulate the goals with respect to the education and the skills of the laboratory personnel. The training program is relevant to the present and anticipated tasks of the laboratory. SOP# QSP 5-2-1 is utilized to identify training needs and providing the necessary training for personnel.

Details:
The skills and knowledge are defined in the job description for each job function as described in section 5.2.4. Management compares the job description to the skills and knowledge of the new incumbent to determine the training needs.

Training in the laboratory must include all methods or parts of methods and techniques that personnel are asked to perform. Minimally, the analyst must demonstrate competency by observation by management and verification using replicate and/or check samples. For technicians who perform only parts of the method, confirmation of competency may be verified by observation only. Re-verification of all personnel must be performed annually on all methods or techniques pertinent to their job description.

In some cases it may be appropriate to define competence related to a particular technique or instrument rather then methods. If so, it will be necessary to define for each method, the necessary technique-based competence required together with any additional requirements.

5.2.3 Employees

Policy:

Competent permanent or contractual employees are employed in the laboratory. The technical manager ensures that contractual, additional technical employees, and key support personnel are supervised and work in accordance to the policies and procedures of this Quality Manual.

Details:
Testing must be either performed or supervised by an experienced person qualified to degree level. Personnel have relevant practical work experience (at least 2 years) before being allowed to perform accredited work.

5.2.4 Job Descriptions

Policy:
Current job descriptions for managerial, technical and key support personnel involved in tests and/or calibrations are maintained centrally in the administration area of the laboratory.

Details:
Minimum contents of job descriptions include:
- the duty of performing tests and/or calibrations
- the act of planning tests and/or calibrations and evaluation of results
- the responsibility of developing and validating new methods as / when requested
- expertise and experience
- qualifications and training programs
- managerial duties

Job descriptions are dated and signed to demonstrate that each incumbent has read it and is in agreement. They are maintained current.

5.2.5 Authorized Personnel

Policy:
Management authorizes specific personnel to perform particular types of sampling, test and/or calibration, to issue test reports and calibration certificates, to give opinions and interpretations and to operate particular types of equipment. Records of the relevant competence, educational and professional qualifications, training, skills and experience of all technical personnel and contracted personnel are maintained. This information is readily available and includes the date on which authorization and/or competence was confirmed and the criteria on which the authorization is based and the confirming authority.

Details:
The purpose of these records is to provide evidence that personnel have been adequately trained and their competence to perform particular tests has been assessed. In some cases it may be pertinent to state any particular limitations to competence. The records are maintained in a registry of skills and include:
- academic and professional qualifications
- external and internal courses attended
- relevant on-the-job training and retraining as necessary (i.e., demonstration of competence)
- skills and experience (i.e., resume)
- relevant authorizations

Records are held centrally in the administration area.

Revision History

Revision 0

5.3 Accommodation and Environmental Conditions

The Ten Second Tutorial

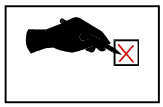
This section tells you:

1. That laboratory facilities are suitable for attaining correct performance of tests and calibrations
2. Critical environmental conditions are monitored, controlled and recorded
3. Incompatible activities are separated
4. Access to laboratories is controlled
5. Good housekeeping is practiced

Key Words

Incompatible activities
Prevent cross-contamination
Controlled access

Cross-references



ISO 17025:1999 Section 5.3

ISO 9001:2000 Section 6.3, 6.4, 7.1, 7.5.1, 7.5.2, 7.6, 8.2.3

5.3.1 Facility

Policy:
Laboratory facilities are appropriate to attain correct performance of tests and/or calibrations. This may include, but not limited to, energy sources, lighting, heating, ventilation and any other environmental conditions.

Appropriate care is taken to ensure that the environment does not invalidate the results or adversely affect the required quality of any measurement. Particular care is taken when sampling, tests and/or calibrations are undertaken at sites other than a permanent laboratory facility. The technical requirements for accommodation and environmental conditions that can affect the results of tests and calibrations are documented.

Details:
This section deals with the test areas in the laboratory and premises for support such as sample receipt and storage. Central laboratory supplies and services, such as water purification systems, air supply, vacuum source, and sample storage, are appropriate to facilitate proper performance of tests.

5.3.2 Monitoring

Policy:
Critical environmental conditions are monitored, controlled and recorded as required by the relevant specifications, methods, and procedures or where they may influence the quality of the results. Due attention is paid, for example, to biological sterility, dust, air quality, electromagnetic interference, radiation, humidity, electrical supply, temperature, and sound and vibration levels, as appropriate to the technical activities concerned. Tests and calibrations are stopped when the environmental conditions jeopardize the results of the tests and/or calibrations.

Details:
Laboratories are ventilated to reduce the levels of contamination, lower humidity, and control temperature. Laboratories' test areas are air-conditioned. The relative humidity in test areas is 45-50 % RH and the temperature is 20-25 °C. Aerial microorganisms are controlled by air systems with filters. Verification is done using air sampling devices or air settling plates and surface swabs.

Bench tops and floors are made of impervious, smooth easily cleaned materials. There is at least two linear meters workspace per analyst while working. Walls and ceilings are made of materials that are smooth and easily cleaned. Critical work surfaces are monitored for pathogens where pertinent to the scope of the laboratory.

If appropriate, the SOP#[PROCEDURE#] is used.

5.3.3 Separation of Incompatible Activities

Policy:
Effective separation between neighboring areas is made when the activities are incompatible. Measures are taken to prevent cross-contamination.

Details:
Reference materials and certified reference materials must be kept separated from samples (log-in and storage). Sample log-in and storage must be segregated, ideally in a separate area from the testing laboratory, and include proper sanitation to exclude the possibility of cross-contamination. Segregation of activities is achieved through time and space allocations.

An example of space segregation would be for a trace analysis. Physical separation of the trace analysis from high-level analysis is achieved through the use of separate rooms.

An example of time segregation would be the coordination of activities at different times. It may be appropriate to perform work on “cleaner” samples first before starting “dirtier” type samples.

5.3.4 Controlled Access

Policy:
Access to and use of areas affecting quality of the tests and/or calibrations is defined and controlled.

Details:
Access to the laboratory is restricted to authorized personnel. The authorized personnel are made aware of the following items:

- the intended use of the area
- the restrictions imposed on working within such areas
- the reasons for imposing the restrictions

5.3.5 Good Housekeeping

Policy:
Measures are taken to ensure good housekeeping in the laboratory. Special procedures are prepared when necessary.

Details:
Controlled use of cleaning and pest control materials is exercised. The laboratory complies with the local health and safety requirements. If appropriate, the SOP#[PROCEDURE#] is used.

Revision History

Revision 0

5.4 Tests and Calibration Methods and Method Validation

The Ten Second Tutorial

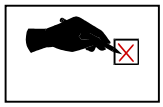
This section tells you:

1. Preference is given to the use of a standard method when selecting procedures
2. All methods must be validated before use
3. Measurement uncertainty is estimated
4. Data is controlled

Key Words

Standard Methods
Laboratory-Developed Methods
Non-standardized Methods
Validation
Uncertainty of Measurement
Data Checks

Cross-references



ISO 17025:1999 Section 5.4

ISO 9001:2000 Section 4.2.1, 4.2.3, 6.3, 6.4, 7.1, 7.2.1, 7.3, 7.4.3, 7.5.1, 7.5.2, 7.6, 8.1, 8.2.3, 8.2.4

5.4.1 General

Policy:
Methods and procedures used for all tests and/or calibrations are appropriate as per:
- sampling, handling, transport, storage, and preparation of items to be tested and/or calibrated
- an estimation of the measurement of uncertainty as well as statistical techniques for analysis of test and/or calibration data where appropriate

Instructions on the use and operation of all relevant equipment and on the handling and preparation of items for testing and/or calibration are available. All instructions, standards, manuals and reference data relevant to the work of the laboratory are maintained current and readily available to personnel. Deviation from test and calibration methods must be documented, technically justified, authorized, and accepted by the client.

Details:
There are SOPs for sampling, sample handling, transport, storage, preparation of test items, QA/QC procedures (media QC, incubation times and temperatures, equipment calibration and maintenance, process control QC), and standards for approving / rejecting results. These may be combined with or separate from the method. The content of a test method includes:
- scope
- description of test items
- holding times
- quantities to be tested
- materials and equipment required
- physical environmental conditions required (incubation times and temperatures, pH requirements)
- description of procedures
- sample identification
- method of recording observations and results
- safety measures
- documentation
- method for data analysis and presentation
- sensitivity of method
- quality control plan

International, national, or regional standards or other recognized specifications that contain sufficient and concise information on how to perform the tests and/or calibrations are not necessarily supplemented or rewritten as an internal procedure when they are written in a way that can be used as published by laboratory staff. Consideration may need to be given to providing additional documentation for optional steps in the method.

5.4.2 Selection of Methods

Policy:
Test and/or calibration methods, including methods for sampling, meet the needs of the client and are appropriate for the tests and/or calibrations it undertakes. Preference is given to reference methods published as international, national, or regional standards. The laboratory ensures that the latest edition of a standard is used unless it is not appropriate or possible to do so. When necessary, the standard is supplemented with additional details to ensure consistent application.

Details:
Methods that have been published either in international, national, or regional standards, or by reputable technical organizations, or in relevant scientific texts or journals, or as specified by the manufacturer are selected when the client does not specify the method to be used. These methods may be adopted from the AOAC, FDA BAM, USDA FSIS & AMS, APHA SMEDP, APHA Compendium of Methods for the Microbiological Examination of Foods, ISO, ICMSF, National Food Processors, American Association of

Cereal Chemists, Association of Dressing and Sauces, Health Canada, Environmental Protection Agency, OIE, ASTM, etc.

The ability of the laboratory to achieve satisfactory performance against documented performance characteristics is verified before samples are analyzed.

Laboratory-developed methods or methods adopted by the laboratory may also be used if they are appropriate for the intended use and if they are validated. The client is informed as to the method chosen. The laboratory confirms that it can properly operate standardized methods before introducing the tests or calibrations. If the standardized method changes, the confirmation is repeated.

The client is informed when the method proposed by the client is considered to be inappropriate or out of date.

5.4.3 Laboratory-Developed Methods

Policy:
Introduction of test and calibration methods developed internally is a planned activity and is assigned to qualified personnel equipped with adequate resources. Plans are updated as development proceeds and ensures effective communication amongst all personnel involved.

Details:
Methods developed in-house are validated and authorized before use. Where available, Certified Reference Materials (CRMs) are used to determine any systemic bias, or where possible results are compared with other techniques, preferably based on different principles of analysis. Determination of uncertainty must be part of this validation process and is essential for ongoing quality control.

5.4.4 Non-Standard Methods

Policy:
Utilization of non-standard methods is subject to agreement with the client and includes a clear specification of the client's requirements and the purpose of the test and/or calibration. The developed method is validated appropriately before use.

Details:
Discussion and agreement for the use of non-standard methods is recorded as part of contract review procedures (see section 4.4).

All non-standard and new tests are validated for their intended purpose. Qualitative test methods must be validated to demonstrate estimated sensitivity and specificity, relative accuracy to official methods (if appropriate), positive and negative deviation, limit of detection, matrix effect, repeatability, and reproducibility.

Quantitative test methods are validated to demonstrate specificity, sensitivity, relative accuracy, positive and negative deviation, repeatability, reproducibility, and limit of determination.

For new methods where procedures are developing rapidly, especially for emergency situations, it may be necessary to circumvent normal validation procedures. Minimally, this must be a demonstrated recovery in replicate.

New test and/or calibration methods are documented prior to providing test and/or calibration results to clients and contain at least the following information:

- appropriate identification
- scope

- description of the type of item to be tested or calibrated
- parameters or quantities to be determined
- apparatus and equipment, including technical performance requirements
- reference standards and reference materials required
- environmental conditions required and any stabilization period needed
- description of the procedure, including
  - affixing identification marks, handling, transporting, storing and preparing of items
  - ensuring checks are made before the work is started
  - checking that the equipment is working properly and, where required, calibrating and adjusting the equipment before each use
  - listing method of recording the observations and results
  - indicating any safety measures to be observed
- criteria and/or requirements for approval/rejection (quality control plan)
- data to be recorded and method of analysis and presentation
- uncertainty or procedure for estimating uncertainty

5.4.5 Validation of Methods

5.4.5.1 Performance Characteristics

Policy:
Validation of a method establishes, by systematic laboratory studies, that the performance characteristics of the method meet the specifications related to the intended use of the test results.

Details:
The performance characteristics of a validation plan includes, as applicable:
- selectivity and specificity
- range
- linearity
- sensitivity
- limit of detection
- limit of quantitation
- ruggedness
- accuracy
- precision
- reporting limit
- repeatability
- reproducibility
- recovery
- confirmation techniques
- criteria for the number of samples tested to validate method as per defined scope of method
- action levels where defined by regulation
- quality control incorporating statistics as applicable
- interpretation of population results as applicable

Performance characteristics that are selected take into account the intended use of the method, whether for screening, confirmatory analysis, or quantitation.

The design, verification of the method and documentation procedures for validation are planned and conducted by qualified personnel, equipped with adequate resources.

This section lists a few acceptable validation procedures. The choice of the procedure depends on the extent of the deviation from the published method.

Validation of methodology is a value judgment in which the performance parameters of the method are compared with the requirements for the test data. A prerequisite for a valid method is that data produced by the method must attain a state of statistical control. Such a state is obtained when the mean value of a large number of individual values tends to approach a limiting value called the limiting mean.

Methods may be validated by one or more alternative procedures. Some of these procedures are described below. Apparent differences can be analyzed statistically to confirm their significance. In all cases, the reasons for choosing one or more alternatives must be documented.

- analysis of standard reference materials (SRM) that are identical or almost identical to the test samples
- in the absence of suitable SRMs, analysis of reference materials that are similar in all respect to the test samples; the use and validity of this reference material must be documented
- using an alternative method to measure the same parameter provides a very high level of confidence if results are confirmed
- recovery studies by the addition of a known concentration of the parameter of interest to some of the replicates being measured

The parameters to be determined include:

- the scope of the method and any known interference
- detection limit
- the range of concentration where the method is valid
- precision and bias
- intra-laboratory variations
- inter-laboratory variations

Judgment is required to determine if some or all of the above is required. Requirements will depend largely on the extent of deviation from the original method.

Developments in methodology and techniques require methods to be changed from time to time. The difference in performance between revised and obsolete methods is established so that it is possible to compare old and new data.

Where a change in method involves only minor adjustments, such as sample size, or different reagents, the amended method is validated and the changes brought to the attention of the accreditation body at the next accreditation audit. Where the proposed change involves technology or methodology, the laboratory seeks the approval of the accreditation body.

Records are kept on all validation activities. The records include any of the performance characteristics chosen, reference procedures or guidance documents followed to validate the method or custom validation procedure, and a final confirmation (memo to file) that the method validation results are acceptable for continued use of the method. An example statement would be “This memo serves as record that the validation of the XYZ Test Method has been approved for use by [name and title of approver]”.

5.4.5.2 Fit for Use

Policy:
The laboratory validates non-standardized methods, laboratory-designed/developed methods, standardized methods used outside their intended range, and amplifications of standard methods to confirm that the methods are fit for the intended use. The validation is as extensive as is necessary to meet the needs in the given application or field of application (may include procedures for sampling, handling, and transportation). The laboratory records the results obtained, the procedure used for the validation, and a statement as to whether the method is fit for the intended use.

Details and Procedure:
Validation records are kept as in section 5.4.5.1. Included in these records is the validation procedure. The procedure used for the validation is likely to vary between different methods. Therefore, the procedures

included in the laboratory records are not as detailed as a typical SOP, but are sufficient enough to re-create how the method was validated.

The techniques used for the determination of the performance of a method, are one of, or a combination of, the following:

- calibration using reference standards or reference materials
- comparison of results achieved with other methods
- inter-laboratory comparisons
- systematic assessment of the factors influencing the result
- assessment of the uncertainty of the results based on scientific understanding of the theoretical principles of the method and practical experience.

When changes are made in the validated non-standard method, the influence of such changes carried out is documented and if appropriate a new validation is performed.

5.4.5.3 Client's Needs

Policy:
The range and accuracy of the values obtainable from validated methods (e.g., the uncertainty of the results, detection limit, selectivity of the method, linearity, limit of repeatability and/or reproducibility, robustness against external influences and/or cross-sensitivity against interference from the matrix of the sample/test object) as assessed for the intended use is relevant to the client's needs.

Details:
Validation includes the specification of the requirements, determination of the characteristics of the methods, the comparison of the requirements with the values of the characteristics of the method, and a statement on the validity.

As method development proceeds, regular review is required to verify that the needs of the client are still being fulfilled. Changing requirements requiring modifications to the development plan are approved and authorized.

Validation is always a balance between costs, risks, and technical possibilities.

5.4.6 Uncertainty of Measurement

5.4.6.1 Calibration

Policy:
Physical, chemical, and biological standards are calibrated or characterized by qualified subcontractors.

Details and Procedures:
Repeatability and reproducibility data are components of measurement uncertainty and are determined as a first step towards producing estimates of this parameter. The uncertainty of measurement is available on the certificate of analysis or calibration certificate from a subcontractor.
Note - in-house calibrations include procedures for uncertainty of measurement estimates where this is common practice.

5.4.6.2 Testing

Policy:
The SOP# QSP 5-4-1 is utilized to estimate uncertainties of measurement in testing, except when the test methods preclude such rigorous calculations. In certain cases it is not possible to undertake metrologically

and statistically valid estimations of uncertainty of measurement. In these cases the laboratory attempts to identify all the components of uncertainty and make the best possible estimation, and ensure that the form of reporting does not give an exaggerated impression of accuracy. Reasonable estimation is based on knowledge of the performance of the method and on the measurement scope and makes use of previous experience and validation data.

Details:
The degree of rigor needed in an estimation of uncertainty of measurement depends on factors such as:
- requirement of the test method
- requirement by the client
- if there are narrow limits on which decisions on conformance to a specification are based

In cases where a well-recognized test method specifies limits to the values of the major sources of uncertainty of measurement and specifies the form of presentation of calculated results, the laboratory is considered to have satisfied the estimation uncertainty of measurement by following the reporting instructions (see section 5.10).

5.4.6.3 Uncertainty Components

Policy:
When estimating the uncertainty of measurement, all uncertainty components that are of importance in the given situation are taken into account using accepted methods of analysis.

Details:
Sources contributing to the uncertainty include, but are not necessarily limited to, the reference standards and reference materials used, methods and equipment used, the environmental conditions, the item being tested or calibrated and the operator.

The predicted long-term behavior of the tested and/or calibrated item is normally not taken into account when estimating the measurement uncertainty.

For further information, see ISO 5725 and the Guide to Expression of Uncertainty in Measurement.

5.4.7 Control of Data

5.4.7.1 Calculations and Data Transfers

Policy:
Calculations and data transfers are subject to appropriate checks in a systematic manner.

Details:
Test data are validated through the following arrangements by the Technical Manager / Corporate Metrologist:
- checks to determine accuracy of calculations, conversions, and data transfers
- checks for transcription errors, omissions, and mistakes
- checks to determine consistency with normal or expected values

For those analyses where manual data reduction is required, it is performed according to the instructions provided in the test method or SOP.

5.4.7.2 Computers and Automated Equipment

Policy:

When computers or automated equipment are used for the acquisition, processing, manipulation, recording, reporting, storage or retrieval of test or calibration data, the laboratory ensures that:

- computer software developed by the user is documented in sufficient detail and suitably validated or otherwise checked as being adequate for use
- procedures are established and implemented for protecting the integrity of data; such procedures include, but not be limited to, integrity and confidentiality of data entry or collection, data storage, data transmission, and data processing (see section 4.12.1.4)
- computers and automated equipment are maintained to ensure proper functioning and are provided with the environmental and operating conditions necessary to maintain the integrity of test and calibration data
- data is securely maintained by preventing unauthorized access to, and unauthorized amendment of, computer records

Details and Procedures:
Data generated using computer software programs that are interfaced directly to instruments incorporates all dilutions and calculations, thereby eliminating the need for manual data reduction.

Commercially developed software in general use within its designed application range may be considered sufficiently validated. Laboratory software configuration / modifications are validated as outlined in SOP# QSP 5-5-1.

Electronic records, electronic signatures, and handwritten signatures executed to electronic records must be equivalent to proper records and handwritten signatures to paper and are validated by procedures in 21 CFR. Part II (Docket No. 92NO251) RIN0910-AA29; Federal Register: March 20, 1997, Volume 62, Number 54), Rules and Regulations, pages 13429-13466. For further details see:

http://www.fda.gov/cder/esig/index.htm

Revision History

Revision 0

5.5 Equipment

The Ten Second Tutorial

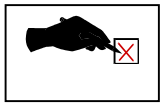
This section tells you to:

1. Identify information needs for accept / reject decisions
2. Install equipment capable of providing that information
3. Use the equipment in the proper environment
4. Periodically check the equipment calibration

Key Words

Required Equipment and Accuracy
Authorized Personnel
Unique Identification
Inventory
Maintenance
Procedures
Out of Service
Calibration Status
Re-verification
Checks
Correction Factors
Safeguards against Adjustment

Cross-references



ISO 17025:1999 Section 5.5

ISO 9001:2000 Section 4.2.1, 4.2.3, 5.1, 7.1, 7.4, 7.5.1, 7.5.2, 7.5.3, 7.6, 8.1, 8.2.3, 8.2.4

5.5.1 Required Equipment

Policy:
The laboratory is furnished with all items for sampling, measurement and test equipment required for the correct performance of the tests and/or calibrations (including sampling, preparation of test and/or calibration items, processing and analysis of test and/or calibration data). When equipment is used outside the laboratory's permanent control, it ensures that the requirements of this Quality Manual are met.

Details:
Equipment is used in an environment appropriate to its proper performance. All equipment required by a test is described in each method, including the equipment's tolerances.

5.5.2 Required Accuracy

Policy:
Equipment and software used for testing, calibration and sampling are capable of achieving the accuracy required and comply with specifications relevant to the tests and/or calibrations concerned. Calibration programs are established for key quantities or values of the instruments where these properties have a significant affect on the results. When received, equipment, including that used for sampling, is checked to establish that it meets the laboratory's specification requirements, complies with the relevant standard specifications, and is checked and/or calibrated in accordance with section 5.6 before use.

Details:
The procedures for checking newly received equipment are as determined by manufacturers' specification and/or those determined by the laboratory during procurement.

5.5.3 Authorized Personnel

Policy:
Equipment is operated by authorized personnel. Up-to-date instructions on the use and maintenance of equipment (including any relevant manuals provided by the manufacturer of the equipment) is readily available for use by the appropriate laboratory personnel.

Details:
Access to laboratory equipment is controlled to ensure that only authorized personnel use equipment.

5.5.4 Unique Identification

Policy:
Each item of equipment used for testing and calibration is uniquely identified as appropriate.

Details:
Measuring and testing equipment is uniquely identified through an asset {number / identification}.
Measuring and testing equipment includes any instrument that could affect the quality of test results.
Components that can be interchanged between various instruments are tracked in equipment logbooks, but are not assigned individual asset {numbers / identifications}.

5.5.5 Inventory and Maintenance Records

Policy:
Records are maintained of each item of equipment significant to the tests and/or calibrations performed. The records include the following:

- identity of the item of equipment (and its software)
- manufacturer's name, type identification, and serial number and/or other unique identification
- checks that equipment complies with the specification (see section 5.5.2)
- current location, where appropriate
- the manufacturer's instructions, if available, or reference to their location
- dates, results and copies of reports and certificates of all calibrations, adjustments, acceptance criteria, and due date of next calibration
- maintenance carried out to date and the maintenance plan (includes calibration)
- damage, malfunction, modification or repair to the equipment

Details:
A database is used to capture the above inventory information. The above information related to service and maintenance is kept in individual equipment files and/or binders. Other information kept in these files and/or binders may include:
- date received and date placed in service
- condition when received (e.g., new, used, refurbished)
- dates and results of calibration and/or verification and date of next calibration and/or verification
- performance history, where appropriate (e.g., response time, drift, noise level)

5.5.6 Equipment Procedures

Policy:
The SOP# QSP 5-5-1 is utilized as an established plan for safe handling, transport, storage, use and maintenance (including calibration) of measuring equipment, and appropriate use of correction factors to ensure proper functioning and in order to prevent contamination or deterioration.

Note – additional procedures may be necessary when measuring equipment is used outside the permanent laboratory for tests, calibrations, or sampling (currently not applicable at our laboratory).

Details and Procedures:
The procedures for each piece of measuring equipment are located in the appropriate room where the equipment is located. These procedures detail any information for safe handling, transport, storage, use, and maintenance of measuring equipment.

5.5.7 Out of Service Equipment

Policy:
Equipment that has either been subjected to overloading or mishandling, or gives suspect results, or has been shown to be defective or outside specified limits, is taken out of service, clearly marked, and appropriately stored until it has been repaired and shown by calibration or test to perform correctly.

Details:
Routine testing work is completely discontinued on equipment that even shows minor nonconformances. Not only do we do this for ethical reasons in support of our client, but minor nonconformances are often indicative of major breakdowns in expensive equipment. These breakdowns need to be avoided wherever possible.

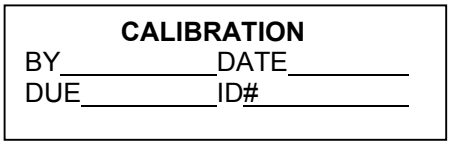
Out of service equipment is clearly marked as outlined in section 5.5.8.

The laboratory examines the effect of the defect or departure from specified limits on previous test and/or calibrations and institutes the "Control of Nonconforming Work" procedure as outlined in section 4.9.

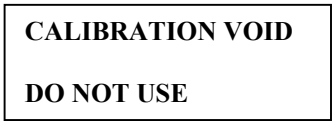
5.5.8 Calibration Status

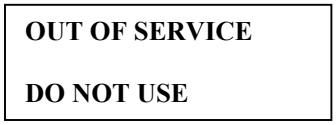
Policy:
Equipment requiring calibration is labeled to indicate the calibration status and/or operational status and the date when re-calibration is due when appropriate.

Details:
Calibration labels have a write-on surface and a pressure sensitive adhesive. The areas that are filled out include the person who performed the calibration, the date it was performed, the date it is due for re-calibration, and the equipment's identification number.



Measuring equipment that has failed calibration or is deemed out of service is labeled with one of the following labels:





A piece of equipment that is not calibrated or checked is labeled with the following label:

5.5.9 Return to Service

Policy:
When equipment goes outside the direct control of the laboratory for a period, the laboratory ensures that the function and calibration status of the equipment are checked and validated and shown to be satisfactory before the equipment is returned to service.

Details and Procedures:
The procedures used to check and ensure that the function and calibration status of the equipment are satisfactory before the equipment is returned to service are outlined in the manufacturer's equipment manual. Any additional quality control checks are outlined in the "Quality Control Plan" section of the appropriate test method.

5.5.10 Periodic Checks

Policy:
When intermediate checks are needed to maintain confidence in the calibration status of equipment, these checks are carried out periodically according to defined procedure.

Details and Procedures:
As stated in section 5.5.6, the procedures for each piece of measuring equipment are located in the appropriate room where the equipment is located. SOP# QSP 5-5-1 outlines a general maintenance plan for equipment and includes various checks. Internal quality control checks are specified in individual test

methods that are located in the appropriate laboratory areas thereby providing procedures for intermediate checks.

5.5.11 Correction Factors

Policy
Calibrations that give rise to a set of correction factors are updated along with all copies of this data (e.g., in computer software).

Details and Procedures:
The updating of correction factors including all copies is assured by following the appropriate test method or SOP. It is the responsibility of the Quality Manager to ensure that all copies are updated.

5.5.12 Safeguards against Adjustments

Policy:
Test and calibration equipment, including hardware and software, are safeguarded from adjustments that invalidate test and/or calibration results/status.

Details:
Safeguards against adjustment for laboratory equipment include:
- detailed SOPs and manufacturer's manuals on the operation of the equipment
- policies permitting only fully trained and competent personnel to operate equipment
- access to the laboratory is restricted to authorized personnel

Safeguards against adjustment for software includes:
- password protection for important files and packages
- access to the laboratory is restricted to authorized personnel

Revision History

Revision 0

5.6 Measurement Traceability

The Ten Second Tutorial

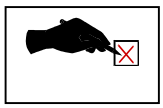
This section tells you:

1. Measurements are traceable to SI units (when applicable)
2. Reference Standards and Reference Materials are used

Key Words

Systèm International
Reference Standard
Reference Material
Traceability

Cross-references



ISO 17025:1999 Section 5.6

ISO 9001:2000 Section 7.1, 7.6

5.6.1 General

Policy:
Test and/or calibration equipment for subsidiary measurements (e.g., for environmental conditions) having a significant effect on the accuracy or validity of the result of the test, calibration, or sampling are calibrated before being put into service. All measurement and test equipment having an effect on the accuracy or validity of tests are calibrated and/or verified before being put into service. As mentioned in section 5.5, the SOP# QSP 5-5-1 outlines an established program for the maintenance of equipment and includes calibration.

Details:
The program includes a system for selecting, using, calibrating, checking, controlling, and maintaining:
- measurement standards
- reference standards used as measurement standards
- measuring and test equipment used to perform tests and calibrations

Procedures are documented where appropriate. All measurements that play a defining role in testing accuracy are based directly or indirectly on reference standards, reference materials, certified reference materials, or other standards or materials having appropriate traceability.

Records are maintained for each standard. These records include, as applicable:
- supplier, grade, batch#
- dates of preparation or verification
- measurement of weights, volumes, time intervals, temperatures, and pressures and related calculations
- relevant processes (e.g., pH adjustment, sterilization)
- verification results
- identification of personnel involved

Reagents prepared in the laboratory are labelled to identify substance, strength, solvent (where not water), any special precautions or hazards, restrictions of use, and date of preparation and/or expiry. The person responsible for the preparation of the reagent is identified either from the label or from records.

5.6.2 Specific Requirements

5.6.2.1 Calibration

Policy:
The program for calibration equipment is designed and operated to ensure that calibration measurements are traceable to the Système International (SI) units of measurement.

Details:
Traceability of measurement is assured by the use of calibration services from laboratories that can demonstrate competence, measurement capability and traceability. The calibration certificates issued by these laboratories show that there is a link to a primary standard or to a natural constant realizing the SI unit by an unbroken chain of calibrations. The calibration certificates contain the measurement results including the measurement uncertainty and/or a statement of compliance with an identified metrological specification (see also section 5.10.4.2).

Calibration laboratories accredited to ISO 17025 are considered competent to provide the appropriate calibration services.

Traceability to SI units of measurement may be achieved by reference to an appropriate primary standard or by reference to a natural constant the value of which in terms of the relevant SI unit is known.

The term "identified metrological specification" means that it must be clear from the calibration certificate against which specification the measurements have been compared with, by including the specification or by giving an unambiguous reference to the specification.

When the terms "international standard" or "national standard" are used in connection with traceability, it is assumed that these standards fulfil the properties of primary standards for the realization of SI units.

Maintain certificates of all reference standards, measuring equipment, or certified reference material used in ensuring traceability. Where traceability to national standards of measurement is not applicable, the laboratory provides satisfactory evidence of correlation of results, for example by participation in a suitable program of inter-laboratory comparisons or proficiency testing.

Reference standards, such as thermometers and weights are traceable to a national or international standard (e.g., NIST).

5.6.2.2 Testing

5.6.2.2.1

Policy:
The requirements given in section 5.6.2.1 apply to measuring and test equipment with measuring functions used, unless it has been established that the associated calibration uncertainty contributes little to the total uncertainty of the test result. When this situation arises, the laboratory ensures that equipment used can provide the accuracy of measurement needed.

Details:
The extent to which the requirements in section 5.6.2.1 are followed depends on the relative contribution of calibration uncertainty to the total uncertainty. If calibration is the dominant factor, the requirements are strictly followed. If, however, calibration is not one of the major contributors to the total uncertainty, other ways for providing confidence may be used, as given in section 5.6.2.2.2.

5.6.2.2.2

Policy:
Where traceability to SI units of measurement is not possible and/or not relevant, other means for providing confidence in the results are applied such as:

- the use of suitable reference materials certified to give a reliable characterization of the material
- mutual-consent standards or methods which are clearly specified and agreed upon by all parties concerned
- participation in a suitable program of inter-laboratory comparisons or proficiency testing

Details:
Reliable characterization involves an estimate of recovery.

The laboratory participates in proficiency testing and/or check sample programs. The list of programs is maintained by the Quality Manager.

5.6.3 Reference Standards and Reference Materials

5.6.3.1 Reference Standards

Policy:
The SOP# QSP 5-6-1 outlines the program for the calibration of reference standards. Reference standards are obtained or calibrated by a body that can provide traceability as described in section 5.6.2.1. Such reference standards of measurement held by the laboratory are used for calibration only and for no other purpose, unless it can be shown that their performance as reference standards would not be invalidated.

Details:
Reference standards are obtained from the National Institute of Standards and Technology (NIST) and the National Research Council (NRC) for certain measurements are available in Canada], if applicable.

5.6.3.2 Reference Materials

Policy:
Where possible, reference materials are traceable to SI units of measurement, or to certified reference materials. Internal reference materials are checked as far as is technically and economically practicable.

Details:
Reference materials, including calibration standards, used in chemical measurement are prepared so that the point of measurement is similar or equivalent to that of the samples. The matrix, prior to the addition of the analyte does not have a detectable concentration of the analyte. Reagents used in the preparation of reference materials, including calibration standards are of certified purity.

5.6.3.3 Intermediate Checks

Policy:
Checks needed to maintain confidence in the calibration status of reference, primary, transfer or working standards and reference materials are carried out according to defined procedures and schedules.

Details and Procedures:
The control check standards used to verify the accuracy of all the other standards are prepared independently from all the other standards used to establish the original calibration. These control check standards are preferably prepared from a separate lot # or source. It is the responsibility of the Quality Manager to establish and maintain the individual schedule for each SOP and/or test method.

5.6.3.4 Transport and Storage

Policy:
The SOP# QSP 5-6-1 outlines safe handling, transport, storage and use of reference standards and reference materials in order to prevent contamination or deterioration and in order to protect their integrity.

Details:
Additional procedures may be necessary when reference standards and reference materials are used outside the permanent laboratory for tests, calibrations, or sampling.

Proper conditions are established for housing, handling, and care of reference standards/reference materials/test samples. Test samples are acclimatized to the test environment for an adequate period before a test is initiated. All information needed to properly identify references appears on their housing or containers.

Revision History

Revision 0

5.7 Sampling

The Ten Second Tutorial

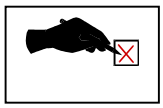
This section tells you:

1. There must be a sampling plan and procedure
2. Appropriate records of sampling are kept
3. Deviations, additions, and exclusions from the plan or procedure are recorded

Key Words

Sampling Plan and Procedure
Deviation, Addition, or Exclusion

Cross-references



ISO 17025:1999 Section 5.7

ISO 9001:2000 Section 4.2.4

5.7.1 Sampling Plan and Procedures

Policy:
The SOP# QSP 5-7-1 outlines the sampling plan and procedures for sampling for any laboratory sampling of substances, matrices, materials or products for subsequent testing or calibration. The sampling plan and procedures are available at the location where sampling is performed. Sampling plans are based on appropriate statistical methods whenever reasonable. The sampling process addresses the factors to be controlled to ensure validity of the test and calibration results.

Details:
Sampling is a defined procedure whereby a part of a substance, matrix, material or product is taken to provide for testing or calibration as a representative sample of the whole. Sampling can also be required by the appropriate specification for which the substance, matrix, material or product is to be tested or calibrated. In certain cases (e.g., forensic analysis), the sample may not be representative, but determined by availability.

The sampling plan describes the allocation, withdrawal and preparation of a sample or samples from a substance, matrix, material or product to yield the required information. All samples are collected and placed in sealed containers.

5.7.2 Deviations, Additions or Exclusions

Policy:
Where the client requires deviations, additions or exclusions from the sampling procedure, these are recorded in detail with the appropriate sampling data and included in all documents containing test and/or calibration results, and communicated to the appropriate personnel.

Details:
The physical appearance and temperature of all test items is observed and recorded upon receipt. Any deviations from specifications or observations are discussed with the client as to the suitability of the sample. Cross-contamination is the most critical issue from broken, leaking samples for both qualitative and quantitative tests.

5.7.3 Records

Policy:
The SOP# QSP 5-7-1 outlines the procedures for recording relevant data and operations relating to sampling that forms part of the testing or calibration that is undertaken. These records include the sampling procedure used, the identification of the sampler, environmental conditions (if relevant) and any diagrams or other equivalent means to identify the sampling location as necessary, and, if appropriate, the statistics upon which the sampling procedures are based.

Details:
Adequate sample identification upon receipt in the laboratory includes:
- unique and unambiguous sample identification, usually a number or alphanumeric identification, retained throughout the testing life of the test item
- name of person(s) the report will be sent to
- sample source and date if available
- identification number or description from (client) if any
- product description
- tests desired and/or methods requested
- date of receipt
- delivery carrier
- sample condition, including temperature

Revision History

Revision 0

5.8 Handling of Test and Calibration Items

The Ten Second Tutorial

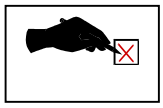
This section tells you to:

1. Keep samples in good condition.

Key Words

Identification
Receipt
Protection

Cross-references



ISO 17025:1999 Section 5.8

ISO 9001:2000 Section 6.3, 6.4, 7.1, 7.4.3, 7.5, 8.2.4

5.8.1 Procedures

Policy:
The SOP# QSP 5-8-1 outlines the procedures for the transportation, receipt, handling, protection, storage, retention and/or disposal of test and/or calibration items, including all provisions necessary to protect the integrity of the test or calibration item, and the interests of the laboratory and the client.

Details:
Samples, reagents, and standards are stored so as to ensure their integrity by preventing against deterioration, contamination, and loss of identity. It is recognized that this is a general statement, but details are elaborated upon in SOP# QSP 5-8-1.

5.8.2 Identification of Test and/or Calibration Items

Policy:
Test and/or calibration items are systematically identified as they arrive at the laboratory. The identification is retained throughout the life of the item in the laboratory. The system is designed and operated so as to ensure that items cannot be confused physically, or when referred to in records or other documents. The system accommodates a sub-division of groups of items and the transfer of items within and from the laboratory when appropriate.

Details:
Sample labelling indicates the unique identification and conforms to applicable legal requirements. Where conformity of possession of a test sample must be maintained for forensic or other purposes, the laboratory establishes and documents a system for appropriate chain-of-custody (forensic samples may be used in a court of law for evidentiary purposes).

5.8.3 Receipt

Policy:
Upon receipt of the test or calibration item, any abnormalities or departures from normal or specified conditions, as described in the relevant test or calibration method, are recorded. When there is any doubt as to the suitability of an item for test or calibration, or when an item does not conform to the description provided, or the test or calibration required is not specified in sufficient detail, the laboratory consults the client for further instructions before proceeding and keeps a record of the discussion.

Details:
Conform to applicable regulations or contractual arrangements. The condition of sample may include or relate to damage, quantity, preparation, packaging, or temperature. Preparation may include addition of chemical preservative, removal of moisture, isolation of portion of sample to be tested, homogenization, or subsampling.

Arrangements are in place to ensure that elapsed time between sampling and testing does not exceed test method specifications (holding time).

5.8.4 Protection

Policy:
The SOP# QSP 5-8-1 outlines the procedures and appropriate facilities for avoiding deterioration, loss or damage to the test or calibration item during storage, handling and preparation and testing; instructions provided with the item are followed. When items have to be stored or conditioned under specified environmental conditions, these conditions are maintained, monitored, and recorded. Where a test item is to be held secure (e.g., for reasons of record, safety or value, or to enable complementary test and/or calibrations to

be performed later), the laboratory has arrangements for storage and security that protect the condition and integrity of the secured item concerned.

Details:
Where test items are to be returned into service after testing (e.g., for non-destructive testing or human beings subject to medical tests), special care is required to ensure that they are not damaged or injured during the handling, testing or storing/waiting processes.

A sampling procedure and information on storage and transport of samples, including all information that may influence the test or calibration result, is provided to those responsible for taking and transporting the samples.

The laboratory establishes whether the sample has received all necessary preparation or whether the client requires preparation to be undertaken or arranged by the laboratory. Proper requirements for packaging, environmental conditions, and separation from incompatible materials are observed. Where samples have to be stored or conditioned under specific conditions, these conditions are maintained, monitored, and recorded, where necessary.

Where a sample, or portion of a sample, is to be held secure (e.g., for reasons of record, safety, or value, or to enable check tests to be performed later), the laboratory has storage and security arrangements that protect the condition and integrity of the sample.

Revision History

Revision 0

5.9 Assuring the Quality of Test and Calibration Results

The Ten Second Tutorial

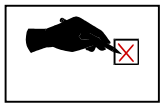
This section tells you:

1. That results are monitored
2. There is a plan for monitoring

Key Words

Internal Quality Control
Statistical Techniques
Inter-laboratory Comparisons
Proficiency Testing
Certified Reference Materials
Secondary Reference Material
Replicates
Re-testing
Correlation

Cross-references



ISO 17025:1999 Section 5.9

ISO 9001:2000 Section 6.3, 6.4, 7.1, 7.4.3, 7.5.1, 7.5.2, 7.5.3, 7.5.5, 8.1, 8.2.3, 8.2.4, 8.4

5.9 Assuring the Quality of Test and Calibration Results

Policy:
Quality control procedures are utilized to monitor the validity of test and/or calibration results. These procedures are for each test method utilized in the laboratory. The resulting data are recorded so that trends are detectable (and where practicable, statistical techniques are applied to the reviewing of the results. This monitoring is planned and reviewed and may include, but not limited to, the following:

- regular use of certified reference materials and/or internal quality control using secondary reference materials
- participation in inter-laboratory comparisons or proficiency testing programs
- replicate tests or calibrations using the same or different methods
- re-testing or re-calibration of retained items
- correlation of results for different characteristics of an item

Details:
The methods utilized from the above list will be appropriate for the type and volume of the work undertaken. Records are maintained of assurance activities and any actions taken.

As a guide, for routine analyses the level of internal quality control is typically 5% of the sample throughput. For more complex procedures, 20% is not unusual and on occasions even 50% may be required. For analyses performed infrequently, a full system validation is performed on each occasion. This may typically involve the use of a reference material containing a certified or known concentration of analyte, followed by replicate analyses of the sample and spiked sample. For analyses undertaken more frequently, systematic quality control procedures incorporating the use of control charts and check samples are implemented. These procedures are documented in the "Quality Control Plan" of each test method.

Internal quality control schemes using statistics include:

- design of experimental/factorial analysis
- variation/regression analysis
- safety evaluation/risk analysis
- tests of significance
- quality control charts
- statistical sampling inspection

Proficiency testing helps to highlight not only repeatability and reproducibility performance between laboratories, but also systematic errors such as bias. It is important to monitor proficiency testing results as a means of checking quality assurance and take action as necessary.

The Quality Manager maintains a list of all the current proficiency testing programs the laboratory participates in, monitors the results, and notifies the appropriate personnel of both problematic and successful results.

Technical personnel use certified reference materials and reference materials to evaluate test performance on a daily basis and include daily process control checks. These data are used to evaluate the validity of the test results.

Replicate tests may be used if suitable reference material is available. These materials and proficiency test materials are available for improving repeatability.

Re-testing of test items is performed occasionally at the discretion of the supervisor or when test results seem anomalous.

Revision History

Revision 0
5.10 Reporting of Results

The Ten Second Tutorial

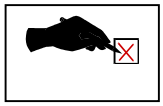
This section tells you:

1. What needs to be on a report
2. How to handle amendments to reports

Key Words

Specific Information
Required Information
Interpretation
Opinion
Subcontractor
Electronic Transmission of Results
Format
Amendments

Cross-references



ISO 17025:1999 Section 5.10

ISO 9001:2000 Section 7.1, 7.4.3, 7.5.1, 7.5.4, 8.2.4

5.10.1 General

Policy:
The results of each test, calibration, or series of tests or calibrations are reported accurately, clearly, unambiguously and objectively, and in accordance with any specific instructions in the test or calibration methods.

The results are reported, normally in a test report or a calibration certificate and include all the information requested by the client and necessary for the interpretation of the test or calibration results and all information required by the method used. This information may include what is outlined in section 5.10.2, 5.10.3 and 5.10.4.

In the case of tests or calibrations performed for internal clients, and in the case of a written agreement with the client, the results may be reported in a simplified way. The information listed in section 5.10.2 to 5.10.4, and not reported, is kept readily available.

Details:
Test reports and/or calibration reports are issued as either hard copy or by electronic data transfer.

5.10.2 Test reports and calibration certificates

Policy:
Test reports and/or calibration certificates include the following information, as appropriate:

- a title (e.g., "Test Report" or Calibration Certificate)
- name and address of laboratory, and location where tests and/or calibrations were carried out if different from the address of the laboratory
- unique identification of the test report or calibration certificate (such as a serial number), and on each page an identification in order to ensure that the page is recognized as a part of the test report or calibration certificate, and a clear identification of the end of the test report or calibration certificate
- name and address of the client
- identification of the method used
- description, condition, and unambiguous identification of the item(s) tested or calibrated
- date of receipt of test or calibration items (where this is critical to the validity and application of the results) and date(s) of performance of the test or calibration
- reference to sampling procedures used by the laboratory or other bodies where these are relevant to the validity or application of the results
- test or calibration results with, where appropriate, units of measurement
- the name(s), function(s) and signature(s) or equivalent of person(s) authorizing the test report or calibration certificate
- where relevant, a statement to the effect that the results relate only to the items tested or calibrated

Details:
Signing authority for test reports is the responsibility of the Technical Manager. Records for individuals with signing authority for test reports are approved by the Technical Manager and maintained by the Quality Manager.

Hard copies of test reports [or calibration certificates] include the page number and total number of pages.

A statement is included specifying that the test report or calibration certificate is not to be reproduced except in full, without written approval of the laboratory. Data reported to the client contains the appropriate significant digits for each test method. Low level data are identified as being below specified limits.

5.10.3 Test Reports

5.10.3.1

Policy and Details:
In addition to the requirements listed in section 5.10.2, test reports include the following, where necessary for the interpretation of results:

- deviations from, additions to, or exclusions from the test method, and information on specific test conditions, such as environmental conditions
- where relevant, a statement of compliance/non-compliance with requirements and/or specifications
- where applicable, a statement on the estimated uncertainty of measurement of the test result; information on uncertainty is needed in test reports when its is relevant to the validity or application of the test results, when a client's instruction so requires, or when uncertainty affects compliance to a specification limit
- where appropriate and needed opinions and interpretations (see section 5.10.5)
- additional information required by specific methods, clients, or groups of clients

5.10.3.2

Policy and Details:
In addition to the requirements listed in sections 5.10.2 and 5.10.3.1, test reports containing the results of sampling include the following, where necessary for the interpretation of test results:

- date of sampling
- unambiguous identification of substance, matrix, material or product sampled (including name of manufacturer, model or type of designation and serial numbers as appropriate)
- location of sampling, including any diagrams, sketches or photographs
- reference to sampling plan and procedures used
- details of any environmental condition during sampling that may affect the interpretation of the test results
- any standard or other specification for the sampling method or procedure, and deviations, additions to or exclusions from the specification concerned

5.10.4 Calibration Certificates

5.10.4.1

Policy:
The testing laboratory generally does not issue calibration certificates. However, the laboratory often receives calibration services from a calibration laboratory and needs to be familiar with the information on a calibration certificate.

Details:
In addition to the requirements listed in 5.10.2, the calibration certificate could include the following, where necessary for the interpretation of calibration results:

- the conditions (e.g., environmental) under which the calibrations were made that have an influence on the measurement results
- the uncertainty of measurement and/or a statement of compliance with an identified metrological specification or clauses thereof
- evidence that the measurements are traceable (see 5.6.2.1.1)

5.10.4.2

Policy:
This section is not applicable to a testing laboratory.

For the calibration laboratory - The calibration certificate relates only to metrological quantities and the results of functional tests and specifically states which clauses of the specification are met or not met. When a statement of compliance with a specification is made omitting the measurement results and associated uncertainties, the laboratory records those results and maintains them for possible future reference. When statements of compliance are made, the uncertainty of measurement is accounted for.

Note - When an instrument for calibration has been adjusted or repaired, the calibration results before adjustment or repair, if available, are reported.

5.10.4.3

Policy:
This section is not applicable to a testing laboratory.

For the calibration laboratory - A calibration certificate (or calibration label) does not contain any recommendation on the re-calibration interval except where this has been agreed with the client. This requirement may be superseded by legal regulations.

5.10.5 Opinions and Interpretations

Policy:
When opinions and interpretations are included in the test report, the basis upon which the opinions and interpretations have been made is documented. Opinions and interpretations are clearly marked as such in the test report.

Note - opinions and interpretations should not be mixed-up with inspections and product certifications as intended in ISO/IEC 17020 and ISO/IEC Guide 65.

Details:
Opinions and interpretations included in a test report may comprise, but not be limited to the following:
- opinion on conformity of the results with requirements
- fulfilment of contractual requirements
- recommendations on how to use the results
- guidance to be used for improvements

In many cases it is appropriate to communicate the opinions and interpretations by direct dialogue with the client. This dialogue is written down.

5.10.6 Testing and Calibration Results Obtained from Subcontractors

Policy and Details:
Test reports containing the results of tests performed by subcontractors are clearly identified for the subcontracted results. The subcontractor reports the results either in writing or electronically to our laboratory.

5.10.7 Electronic Transmission of Results

Policy:

In the case of transmission of test or calibration results by telephone, telex, facsimile or other electronic or electromagnetic means, the requirements of the policies and procedures of this Quality Manual continue to apply (see also 5.4.7).

Details:
Reports that are "published" electronically contain the statement that signatures are on file.

5.10.8 Format of Reports

Policy:
The format of reports is designed to accommodate each type of test or calibration carried out and to minimize the possibility of misunderstanding or misuse.

Details:
The layout of the test report or calibration certificate is such that the presentation of the test or calibration data facilitates ease of assimilation by the reader.

The headings are standardized as far as possible.

5.10.9 Amendments to Reports

Policy:
Material amendments to a test report or calibration certificate after issue are made only in the form of a further document, or data transfer, which includes the statement "Supplement to Test Report or Calibration Certificate, serial number...[or as otherwise identified]", or an equivalent form of wording. Such amendments meet all the requirements in this Quality Manual.

Details:
When it is necessary to issue a complete new test report or calibration certificate, it is uniquely identified and contains a reference to the original that it replaces.

Revision History

Revision 0