

Quality Policy Manual

QPM-001

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Quality Policy Manual

1. Introduction

Introduction

The Source Molecular Corporation is pleased to approve the Quality System Manual in compliance with NELAP Standards (2003). The Lab Directors and upper management of the Source Molecular Corporation support fully this whole quality system as described herein.

Organization Overview

The name of this organization is the Source Molecular Corporation. It is located at 4842 SW 74th Court, Miami, FL 33155

The company provides testing services for microbiological samples.

The company was founded in 2002 and employs 2 people.

Mission

The Directors of the Source Molecular Corporation are committed to upholding the highest degree of professionalism and expertise in all aspects of Environmental and Molecular Microbiology. The laboratory focuses on identification of microbial pathogens and indicators found in water and wastewater as well as in identification of potential sources of fecal contamination (Microbial Source Tracking) in environmental waters. The laboratory is committed to producing and reporting sound and verifiable data that can be used by water quality managers and policymakers as tools for remediation and risk assessment.

Quality Policy Manual

2. Quality Policy and Objectives

Policy Statement

The management of the Source Molecular Corporation is committed to good professional practice and to provide analytical services in compliance with stringent standards of quality. All analyses performed by Source Molecular Corp. shall be in accordance with established assurance practices and specific, written testing procedures. All employees shall be familiar with their responsibilities under the program and implement the policies and procedures in their work. The quality manual shall be readily available to all employees and maintained up-to-date along with quality documentation.

Objectives

1. Test results shall be of known quality
2. The precision and accuracy of all test data shall be determined
3. Data acquisition, transfer and report preparation steps shall be documented
4. All reports shall be reviewed for completeness and conformance to the quality system program by the appropriate department head, the lab director or the lab manager.
5. Raw data, quality control data and reports shall be stored and retrievable
6. Sample receiving shall ensure that Source Molecular Corporation sample acceptance policy is met.
7. Samples shall be retrievable until disposal is called for
8. All operations shall be performed in accordance with and in conformance to detailed, documented standard operating procedures.

Test Methods for which Accredited Testing is Being Performed

Pending

Organization Structure

Source Molecular Corp. operates its testing facilities at one location at 4842 SW 74th Court, Miami, FL 33155.

The senior executives responsible for operation are the Lab Directors.

Source Molecular Corporation maintains a written organization chart designating positions and responsibilities of other company officers, managers as shown in the organization chart.

Approved Signatures for Laboratory

All documents bearing SOURCE MOLECULAR CORPORATION letterhead or those which are directly related to business conducted by Source Molecular Corporation, including official reports, legal documents, etc. must be signed by Dr. Troy M. Scott or Thierry Sam Tamers. Documents bearing any other names will not be considered as legal or certified documents.

Organization and Management Structure

Lab Director – Thierry Sam Tamers

Lab Director/QA Officer - Troy M. Scott, Ph.D.

Relationship between Management, Support Services, and Quality System

Dr. Troy Scott serves as director and principal investigator of the laboratory. Dr. Scott is also the laboratory Quality Manager and Technical Director and is responsible for implementing and enforcing standard operating procedures as well as maintaining all calibration and monitoring logs (see 4.1.5.h). Thierry Sam Tamers is owner and Chief Operating Officer of the Source Molecular Corporation

Job Descriptions of Key Staff

Thierry Sam Tamers – Mr. Tamers serves as Chief Operating Officer of the Corporation. Responsibilities include client interaction, reporting, and quality control of all released documents.

Troy M. Scott, Ph.D. – Laboratory Director/Quality Manager – Oversees and validates final results, Implements and enforces all quality assurance/quality control measures. Supervises field collection and processing of samples, and directs the environmental parasitology and molecular biology divisions of the company. Maintains current Quality Manual. Oversees and validates final results, prepares final reports, supervises analyses, serves as director of Research and Development, heads tissue cell culture laboratory, and directs the environmental virology laboratory.

Policy

Executive management of Source Molecular Corp. is responsible for establishing Policy, Objectives, and Commitment to quality.

Quality System and Management Requirements (NELAC Manual Chapter 5.4 – 5.4.1.5)

- 4.1.1 Source Molecular Corporation is an entity that can be held legally responsible.
- 4.1.2 Source Molecular Corporation conducts activities to be compliant with NELAP Standards, the needs of the client, regulators, or recognition bodies.
- 4.1.3 The management system covers all work carried out in the laboratory's permanent location, on-site, and in associated mobile or temporary facility.
- 4.1.4 The organizational structure of Source Molecular Corporation is defined in order to identify potential conflicts of interest. Source Molecular Corporation does not perform activities other than environmental testing.
- 4.1.5 The laboratory shall:
 - a) Provide personnel with the authority and resources to carry out their duties and to identify the occurrence of departures from the quality system or from the procedures for performing environmental tests, and to initiate actions to prevent or minimize such departures.
 - b) Have processes to assure that staff is free from undue internal and external pressures and influences that may adversely affect the quality of their work.
 - c) Protect the client's confidential information and proprietary rights, including the electronic storage and transmission of results.
 - d) Avoid involvement in activities that diminish confidence in competence, impartiality, judgment or operational integrity.
 - e) Define the organization and management structure, as well as relationships between quality management, technical operations, and support services.
 - f) Specify the responsibility, authority and interrelationships of all personnel affecting quality of environmental tests. Documentation shall include a clear description of the lines of responsibility in the laboratory and shall be proportioned such that adequate supervision is ensured.
 - g) Provide adequate supervision of environmental testing staff, including trainees, by persons familiar with methods and procedures, purpose of each environmental test, and with the assessment of the environmental test results.
 - h) Have a technical manager with overall responsibility for the technical operations and provision of resources needed to ensure the required quality of laboratory operations. The technical director shall certify that personnel with appropriate educational and technical background perform all tests for which the laboratory is accredited, and shall meet the requirements specified in the accreditation process himself. This certification shall be documented (see Demonstration of Capability notebook).
 - i) Have a quality manager who is responsible for implementing the quality system and ensuring that it is followed at all times. The quality manager shall have direct access to the highest level of

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management at which decisions are made on laboratory policy or resources. The quality manager may also be the technical director or deputy technical director. The quality manager shall:

- 1) Serve as the focal point for the QA/QC and be responsible for the oversight and/or review of quality control data.
 - 2) Have functions independent from laboratory operations for which they have quality assurance oversight.
 - 3) Be able to evaluate data objectively and perform assessments without outside influence.
 - 4) Have documented training and/or experience in QA/QC procedures and be knowledgeable in the quality system as defined under NELAC.
 - 5) Have a general knowledge of the analytical test methods for which data review is performed.
 - 6) Arrange for or conduct internal audits as per 5.4.13 annually.
 - 7) Notify laboratory management of deficiencies in the quality system and monitor corrective action.
- j) Appoint deputies for key managerial personnel, including technical director and/or quality manager.
- k) Participate in a proficiency test program for purposes of qualifying for and maintaining accreditation.
- l) Establish and maintain data integrity procedures (see 5.11), including:
- 1) Data integrity training.
 - 2) Signed data integrity documentation for all lab employees.
 - 3) In-depth, periodic monitoring of data integrity.
 - 4) Data integrity procedure documentation.

Responsibility

Lab Directors

References

None

Procedures

Policy

Source Molecular Corporation maintains a formal quality system to ensure that testing conform to specified requirements. The quality system is designed to meet NELAC Standards

Quality System Requirements

- 4.2.1 Source Molecular Corporation has established implemented and maintains a quality system appropriate to its scope of activity. The laboratory documents its policies, systems, programs, procedures, and instructions to the extent necessary to assure the quality of the environmental test results. This documentation is communicated to, understood by, available to, and implemented by the appropriate personnel.
 - 4.2.2 Source Molecular Corporation quality system policies and objectives are defined in a quality manual. The overall objectives are documented in a quality policy, and a statement issued under the authority of the Laboratory Directors and includes:
 - a) Management's commitment to good professional practice and quality of its tests. Policies and objectives for, and commitment to, accepted laboratory practices and quality of testing services is defined and documented.
 - b) Laboratory's standard of service.
 - c) Objectives of the quality system. These policies and objectives are documented in a quality manual.
 - d) Requirement that personnel familiarize themselves with the quality documentation and implement the policies and procedures in their work.
 - e) Management's commitment to compliance NELAC requirements.
 - 4.2.3 The quality manual includes or makes reference to supporting procedures including Standard Operating Procedures, and outlines the structure of the documentation used. The quality manual and related quality documentation state the laboratory's policies and operational procedures established in order to meet the requirements of NELAC standards.
 - 4.2.4 The quality manual defines the roles and responsibilities of the technical and quality managers for ensuring compliance with NELAC.
-

Responsibility

Quality Manager – Dr. Troy Scott

References

None

Procedures

Policy

Source Molecular Corporation maintains a formal quality system for establishing and maintaining control.

Quality System Requirements

- 4.3.1 Source Molecular Corporation has procedures to control all documents that form part of its quality system, both internal and external documents.
 - 4.3.2 Document Approval & Issue:
 - 4.3.2.1 Documents issued as part of the quality system are reviewed and approved by authorized personnel. A master list identifying the current revision and distribution of documents in the quality system is used to ensure invalid and obsolete documents are not used.
 - 4.3.2.2 The procedures ensures:
 - a) Authorized editions of documents are available, where necessary, for the effective functioning of the laboratory.
 - b) Documents are periodically reviewed and revised as necessary.
 - c) Invalid and obsolete documents are promptly removed from service, or assured against unintended use.
 - d) Obsolete documents retained are suitably marked.
 - 4.3.2.3 Quality system documents generated are uniquely identified using the date of issue and/or revision identification, page numbering, the total number of pages or a mark indicating the end of the document, and the issuing authority.
 - 4.3.3 Document Changes:
 - 4.3.3.1 Changes are reviewed and approved by the same function that performed the original review. The designated person has access to pertinent background information.
 - 4.3.3.2 Altered or new text is identified, where practical.
 - 4.3.3.3 Hand amendments are clearly marked, initialed and dated. The revised document will be issued as soon as practical.
 - 4.3.3.4 Computerized maintenance for documents is outlined in SOP Q-5.
-

Responsibility

Quality Manager – Dr. Troy Scott

References

SOP Q-5

Procedures

None

Policy

Source Molecular Corporation ensures that all requirements received from the customer are fully understood and that current capability exists to meet all aspects of the customer's requirements prior to the acceptance of the contract.

Quality System Requirements

4.4.1 Policies and procedures for review leading to a contract for environmental testing ensure:

- a) Requirements, including methods to be used, are adequately defined, documented and understood.
- b) Source Molecular Corporation has the capability and resources to meet the requirements. Source Molecular Corporation will inform the client of any indicated potential conflict, deficiency, lack of appropriate accreditation status, or inability on the laboratory's part to complete the client's work.
- c) Appropriate method is selected and can meet the client's requirements. Differences between request or tender and the contract are resolved before any work commences.

4.4.2 Records of reviews and pertinent discussions with clients are maintained.

4.4.3 Review includes any subcontracted work.

4.4.4 Clients are informed of deviation from contract.

4.4.5 Contracts amended after work starts have the same review as the original. Any change in accreditation status will be reported to the client.

Responsibility

Lab Directors

References

None

Procedures

None

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4.5 Subcontracting of Tests and Calibrations

Policy

Source Molecular Corporation does not employ subcontractors.

Quality System Requirements

None

Responsibility

Laboratory Directors

References

None

Procedures

None

Quality Policy Manual

4.6 Purchasing Services and Supplies

Policy

Source Molecular Corporation ensures that products and services obtained for environmental tests conform to specified requirements.

Quality System Requirements

- 4.6.1 Source Molecular Corporation has policies and procedures for selection and purchasing of services and supplies that affect the quality of environmental tests.
 - 4.6.2 Source Molecular Corporation ensures laboratory consumable materials are inspected or otherwise verified as complying with standard specifications or requirements defined in the methods for the environmental tests concerned, before use. Records of actions taken to check compliance are maintained.
 - 4.6.3 Purchasing documents contain data describing the services and supplies ordered and are reviewed and approved for technical content prior to release.
 - 4.6.4 Suppliers of critical consumables, supplies and services are evaluated, and records of the evaluations are maintained. A list of approved suppliers is maintained.
-

Responsibility

Accounts Receivable/Purchasing - Dr. Scott, Mr. Tamers

References

None

Procedures

None

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4.7 Service to the Client

Policy

Source Molecular Corporation ensures that clients are assured of cooperation and service to the extent possible.

Quality System Requirements

Source Molecular Corporation affords clients cooperation to clarify request and monitor performance in relation to the work performed by the laboratory, to the extent that confidentiality of other clients is maintained.

Responsibility

Directors

References

None

Procedures

None

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4.8 Complaints

Policy

Source Molecular Corporation ensures that customer complaints are handled properly.

Quality System Requirements

Procedures exist for handling customer complaints. Records of complaints, investigations, and corrective actions are maintained.

Responsibility

Directors

References

None

Procedures

Complaints are received, documented, and referred to Dr. Scott. Should errors be found, they are corrected and clients are notified. If no errors are found, clients are contacted to investigate the source of the problem or complaint. Corrective actions are taken to assure the accuracy and reproducibility of the results, and the satisfaction of the customer with the testing protocol.

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4.9 Control of Non-conforming Testing

Policy

Source Molecular Corporation ensures that testing that does not conform to specified requirements is prevented from unintended use. Control will provide for identification, documentation, evaluation, segregation, disposition, and notification of areas effected.

Quality System Requirements

- 4.9.1 Procedures exist and are implemented when work or the results of work do not conform to procedures or the requirements of the client.
The policies and procedures shall ensure:
- a) Responsibility and authority for handling of nonconforming work are designated, and actions are defined and taken when nonconforming work is identified.(4.1.2.1)
 - b) Evaluation of the significance of the nonconformance.
 - c) Corrective action is taken immediately, together with any decision about the acceptability of the nonconforming work.
 - d) Where necessary, the client is notified.
 - e) Responsibility for authorizing the resumption of work is defined.
- 4.9.2 If nonconformance can recur, or there is doubt about compliance of the lab's operations with our own policies and procedures, Corrective Action procedure (SOP Q-1) is promptly followed.
-

Responsibility

Directors

References

None

Procedures

Corrective Action (SOP Q-1)

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4.10 Corrective Action

Policy

Source Molecular Corporation utilizes documented procedures for corrective action to eliminate the causes of actual non-conformity.

Quality System Requirements

- 4.10.1 Policies and procedures are established for corrective action and are implemented by the Lab Director.
- 4.10.2 Cause Analysis (CA) is performed to investigate and determine the root cause.
- 4.10.3 Potential Corrective Action is identified, a determination is made to select and implement the appropriate corrective action that is likely to prevent recurrence, ensuring the Corrective Action is appropriate to the magnitude and risk of the problem. Any changes made as a result of the Corrective Action are documented and implemented.
- 4.10.4 Source Molecular Corporation monitors the Corrective Action to ensure that it is effective.
- 4.10.5 Where nonconformance or departures cast doubts on compliance with policies, procedures, or ISO/IEC 17025, the area of activity is audited per 4.13 as soon as possible.
- 4.10.6 Source Molecular Corporation establishes procedures to determine when departures from documented policies, procedures, and quality control have occurred, including:
 - 4.10.6.1 Identifying individuals responsible for assessing each QC data type.
 - 4.10.6.2 Identifying individuals responsible for initiating/recommending corrective actions.
 - 4.10.6.3 Defining how the analyst shall treat a data set if the associated QC measurements are unacceptable.
 - 4.10.6.4 Specifying how out-of-control situations and subsequent corrective actions are to be documented.
 - 4.10.6.5 Specifying procedures for management to review corrective action reports.
- 4.10.7 To the extent possible, samples shall be reported only if all quality control measures are acceptable. If a quality control measure is found to be out of control and the data is to be reported, all samples associated with the failed quality control measure shall be reported with the appropriate laboratory defined data qualifiers.

Responsibility

Deviation from Standard Procedures: Dr. Scott

Corrective Action: Directors/Managers – Dr. Scott

Overview

Unacceptable results - if unacceptable results are obtained with PE or QC samples, tests with additional positive and negative controls are conducted after calibration of all equipment used in the procedure to determine the source of the problem. The laboratory director (T.M. Scott) or Sr. Research Scientist will take corrective action if necessary.

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Departure from documented procedures or standard specifications - If a prescribed methodology is deemed to be inaccurate or unreliable for a particular sample, alternative methodologies will be independently pursued by Dr. Scott. If results from explorative research are consistent, standard procedures may be modified in the existing case. Deviation from standard procedure must be approved by Dr. Scott.

Procedures

Corrective Action (SOP Q-1)

Corrective Action for EPA Method 1623 (SOP Q-7)

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4.11 Preventive Action

Policy

Source Molecular Corporation utilizes documented procedures for preventive action to eliminate the causes of potential non-conformity.

Quality System Requirements

- 4.11.1 Improvements and potential nonconformances are identified. If preventive action is required, plans are developed, implemented and monitored to reduce the likelihood of occurrence and take advantage of opportunities for improvement.
 - 4.11.2 Procedures include initiation of actions and controls to ensure they are effective.
-

Responsibility

Laboratory Manager

References

None

Procedures

None

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4.12 Control of Records

Policy

Source Molecular Corporation maintains accurate records to provide evidence that the quality system elements have been effectively implemented.

Quality System Requirements

4.12.1 General:

- 4.12.1.1 Procedures are established for identification, collection, indexing, access, filing, storage, maintenance and disposal of quality and technical records. These include reports from internal audits, management review and records of the corrective and preventative action process.
- 4.12.1.2 Records are legible and stored to be readily retrievable in suitable environments to prevent damage, deterioration or loss. Retention times of all records will be 5 years. Should the laboratory transfer ownership or go out of business, all records will be stored in a location suitable for all requirements in this section for a period of 5 years.
- 4.12.1.3 Records are held secure and in confidence.
- 4.12.1.4 Procedures to protect and back-up electronic records and prevent unauthorized access are in place.
- 4.12.1.5 The record keeping system allows historical reconstruction of all laboratory activities that produced the analytical data. Documentation allows the history of the sample to be readily understood.
 - 4.12.1.5.1 Records include identity of personnel involved in sampling, sample receipt, preparation, and testing.
 - 4.12.1.5.2 All information relating to laboratory facilities equipment, analytical test methods, and related laboratory activities, such as sample receipt, sample preparation, and data verification, are documented.
 - 4.12.1.5.3 The record keeping system facilitates the retrieval of all working files and archived records for inspection and verification purposes.
 - 4.12.1.5.4 All changes to records are initialed by responsible staff, and the reason for the initials is clearly indicated in the records, such as “sampled by”, “prepared by”, “or reviewed by”.
 - 4.12.1.5.5 All generated data except those that are generated by automated data collection systems are recorded directly, promptly, and legibly in permanent ink.
 - 4.12.1.5.6 Entries in records are not obliterated by methods such as erasures, overwritten files, or markings. Corrections to record-keeping errors (electronic and hard-copy) are made by one line marked through the error, and the individual making the correction initials and dates the correction.
- 4.12.2 Technical Records
 - 4.12.2.1 Source Molecular Corporation retains records of original observations, derived data, and sufficient information to establish an audit trail, calibration, records, staff records, and a copy of each test report issued for a period of three years.
 - 4.12.2.2 Observations, data and calculations are recorded at the time they are made and are identifiable to the specific task.

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- 4.12.2.3 Mistakes are single-line crossed out, correct entry made, and signed or initialed by person making correction. Electronic records are handled to prevent change or loss of original data. When corrections are due to reasons other than transcription errors, the reason for the correction is documented.
- 4.12.2.4 Records management and storage
- 4.12.2.4.1 All records (including those pertaining to test equipment), certificates, and reports are safely stored, held secure, and in confidence to the client. NELAP-related records are available to the accrediting authority.
- 4.12.2.4.2 All records, including those specified in 4.12.2.5, are retained for a minimum of five years from the generation of the last entry in the records. The laboratory maintains all information necessary for the historical reconstruction of data. Records which are stored only on electronic media are supported by the hardware and software necessary for their retrieval.
- 4.12.2.4.3 Records that are stored or generated by computers have hard copy or write-protected backup copies.
- 4.12.2.4.4 Source Molecular Corporation has established a record management system for control of laboratory notebooks, instrument logbooks, standards logbooks, and records for data reduction, validation, storage, and reporting.
- 4.12.2.4.5 Access to archived information is documented with an access log. These records are protected against fire, theft, loss, environmental deterioration, vermin, and, in the case of electronic records, electronic and magnetic sources.
- 4.12.2.4.6 Source Molecular Corporation has a plan to ensure that records are maintained or transferred according to the clients' instructions in the event that the laboratory transfers ownership or goes out of business. In cases of bankruptcy, appropriate regulatory and state legal requirements concerning laboratory records will be followed.
- 4.12.2.5 Laboratory sample tracking
- 4.12.2.5.1 Sample handling: A record of all procedures to which a sample is subjected while in the possession of Source Molecular Corporation is maintained, including:
- 4.12.2.5.1.1 Sample preservation, including appropriateness of sample container and compliance with holding time requirement.
- 4.12.2.5.1.2 Sample identification, receipt, acceptance or rejection and log-in.
- 4.12.2.5.1.3 Sample storage and tracking, including shipping receipts, sample transmittal forms, and chain-of-custody form.
- 4.12.2.5.1.4 Documented procedures for the receipt and retention of samples, including all provisions necessary to protect the integrity of samples.
- 4.12.2.5.2 Laboratory support activities: the following are retained:
- 4.12.2.5.2.1 All original raw data, whether hard copy or electronic, for calibrations, samples, and quality control measures, including analysts' work sheets and data output records.
- 4.12.2.5.2.2 A written description or reference to the specific test method used which includes a description of the specific computational steps used to translate parametric observations into a reportable analytical value.
- 4.12.2.5.2.3 Copies of final reports.
- 4.12.2.5.2.4 Archived SOP's.

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- 4.12.2.5.2.5 Correspondence relating to laboratory activities for a specific project.
- 4.12.2.5.2.6 All corrective action reports, audits, and audit responses.
- 4.12.2.5.2.7 Proficiency test results and raw data.
- 4.12.2.5.2.8 Results of data review, verification, and cross-checking procedures.
- 4.12.2.5.3 Analytical records: essential information associated with analysis, such as strip charts, tabular printouts, compute data files, analytical notebooks, and run logs, includes:
 - 4.12.2.5.3.1 Laboratory sample ID code.
 - 4.12.2.5.3.2 Date of analysis and time of analysis if the holding time is 72 hours or less, or when a time-critical step is included in the analysis, e.g. extractions, incubations.
 - 4.12.2.5.3.3 Instrumentation, identification, and instrument operating conditions/parameters, or reference to such data.
 - 4.12.2.5.3.4 Analysis type
 - 4.12.2.5.3.5 All manual calculations, e.g. manual integrations.
 - 4.12.2.5.3.6 Analyst's/operator's initials.
 - 4.12.2.5.3.7 Sample preparation including cleanup, separation protocols, incubation periods or subculture, ID codes, volumes, weights, instrument printouts, meter readings, calculations, reagents.
 - 4.12.2.5.3.8 Sample analysis.
 - 4.12.2.5.3.9 Standard and reagent origin, receipt, preparation, and use.
 - 4.12.2.5.3.10 Calibration criteria, frequency, and acceptance criteria.
 - 4.12.2.5.3.11 Data and statistical calculations, review, confirmation, interpretation, assessment, and reporting conventions.
 - 4.12.2.5.3.12 Quality control protocols and assessment.
 - 4.12.2.5.3.13 Electronic data security, software documentation and verification, software and hardware audits, backups, and records of any changes to automated data entries.
 - 4.12.2.5.3.14 Method performance criteria including expected quality control requirements.
- 4.12.2.5.4 Administrative records: the following is maintained:
 - 4.12.2.5.4.1 Personnel qualifications, experience, and training records.
 - 4.12.2.5.4.2 Records of demonstration of capability or each analyst.
 - 4.12.2.5.4.3 A log of names, initials, and signatures for all individuals who are responsible for signing or initialing any laboratory record.

Responsibility

Office Manager

References

Procedures

Data reduction - All statistical analyses are performed using analytical computer software. Results are compiled into reports and are stored as a hard copy and in a computer database, and backed up by external electronic storage devices.

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Accuracy of transcriptions - Sample collection sheets and laboratory data sheets are compared and verified before report preparation and are saved and available for confirmation of results.

Data Validation - The laboratory directors will monitor compliance with internal audits and previously set EPA ICR QC requirements

Reporting - copies of all data, reports, and monitoring forms as well as final reports are supplied to the primary investigator and filed for further use.

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4.13 Internal Audits

Policy

Source Molecular Corporation plans and implements internal audits to verify and assess the effectiveness of the company's Quality System.

Quality System Requirements

- 4.13.1 Source Molecular Corporation schedules and conducts annual internal audits of all activities that address all elements of NELAC Certification and the quality system using set procedures. Audits are planned and organized by the Quality Assurance manager and are carried out by trained and qualified personnel who are independent of activity being audited as resources permit. Personnel do not audit their own activities except when it can be demonstrated that an effective audit will be carried out.
 - 4.13.2 When findings cast doubt on operations or validity of results, Source Molecular Corporation will take timely corrective action, and will notify clients in writing if investigations show results may have been affected, such as through identification of defective measuring or test equipment. Clients will be notified within 30 days.
 - 4.13.3 The area of audits performed, findings and corrective actions are recorded. Laboratory management ensures that these actions are discharged within the agreed time frame as indicated in the quality manual or SOP's.
 - 4.13.4 Follow-up activity is verified for implementation and effectiveness of corrective action and records are maintained.
-

Responsibility

Quality Manager

References

Procedures

Internal Audits (SOP Q-)

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4.14 Management Reviews

Policy

Source Molecular Corporation plans and implements management reviews to verify the suitability and the effectiveness of the quality System.

Quality System Requirements

- 4.14.1 Source Molecular Corporation schedules reviews of the quality system and environmental testing activities to insure their continued suitability and effectiveness, and to introduce changes or improvements. These reviews include:
- 4.14.1.1 Suitability of policies and procedures
 - 4.14.1.2 Reports from managers and supervisors
 - 4.14.1.3 Outcome of recent internal audits
 - 4.14.1.4 Corrective and preventive actions
 - 4.14.1.5 Assessments by external bodies
 - 4.14.1.6 Results of inter laboratory comparisons or proficiency tests
 - 4.14.1.7 Changes in volume and type of work
 - 4.14.1.8 Client feedback
 - 4.14.1.9 Complaints
 - 4.14.1.10 Other relevant factors
- 4.14.2 Records the findings and actions that arise from review. Management ensures that actions are carried out in a timely fashion. Source Molecular Corporation has a procedure for review by management, and maintains records of review findings and actions.
- 4.14.3 Source Molecular Corporation insures that a review is conducted with respect to any evidence of inappropriate actions or vulnerabilities related to data integrity. Discovery of potential issues is handled in a confidential manner until such time as a follow up evaluation, full investigation, or other appropriate actions have been completed and the issues clarified. All investigations that result in finding of inappropriate activity are documented and include any disciplinary actions involved, corrective actions taken, and all appropriate notifications of clients. All documentation of these investigation and actions taken are maintained for at least five years.
-

Responsibility

Quality Manager

References

Procedures

Review by management –

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4.15 Departure from Policies, Procedures, or Standards

Policy

Source Molecular Corporation management allows for exceptionally permitting departures from documented policies and procedures or from standard specifications.

Quality System Requirements

4.15.1 Departures from above stated policies, procedures, and specifications will be handled on a case-by-case basis.

Responsibility

Quality Manager

References

None.

Procedures

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Quality Policy Manual

4.16 Protection of Confidentiality and Proprietary Rights

Policy

Source Molecular Corporation management is dedicated to protecting proprietary rights and confidentiality, including national security concerns.

Quality System Requirements

- 4.16.1 All employees of Source Molecular Corporation are verbally informed that they should protect company proprietary rights and client confidentiality.
 - 4.16.2 All sensitive electronic documents are password protected.
-

Responsibility

Quality Manager

References

None.

Procedures

Quality Policy Manual

5.1 General Technical Requirements

Policy

Source Molecular Corporation ensures that various factors are considered to enable an effective delivery of service.

Quality System Requirements

5.1.1 The following factors are recognized by Source Molecular Corporation as contributing to the correctness and reliability of tests and/or calibrations:

5.1.1.1 Human factors

5.1.1.2 Accommodation and environmental conditions

5.1.1.3 Test and calibration methods and method validation

5.1.1.4 Equipment

5.1.1.5 Measurement traceability

5.1.1.6 The handling of test and calibration items

5.1.2 Source Molecular Corporation takes into account these factors while developing test and calibration methods and procedures, in the training and qualification of personnel, and in the selection and calibration of the equipment used.

Responsibility

Laboratory Directors

References

Procedures

Quality Policy Manual

5.2 Personnel

Policy

Source Molecular Corporation ensures the competence of all personnel who perform laboratory activities.

Quality System Requirements

- 5.2.1 Source Molecular Corporation ensures competence of all who operate equipment, perform tests, evaluate results, and sign test reports. While training is in progress, appropriate supervision is provided. Personnel performing specific tasks are qualified based on appropriate education, training, experience and/or demonstrated skills, as required. The laboratory has sufficient personnel with necessary education, training, technical knowledge and experience for their assigned functions. All personnel are responsible for complying with all quality assurance/quality control requirements that pertain to their organizational/technical function. Each technical staff member has a combination of experience and education to adequately demonstrate a specific knowledge of their particular function and a general knowledge of laboratory operations, test methods, quality assurance/quality control procedures and records management.
- 5.2.2 Source Molecular Corporation management formulates goals with respect to the education, training, and skills of the laboratory personnel. Policy and procedures are developed for identifying training needs and providing the training to meet these needs. This program takes into account present and anticipated task the laboratory may have.
- 5.2.3 Source Molecular Corporation uses personnel employed by or contracted to the laboratory. Where contractors or additional key personnel are used, supervision is provided to evaluate competence of work and adherence to the laboratory's quality system.
- 5.2.4 Job descriptions are maintained for managerial, technical and key support personnel involved in tests and calibrations.
- 5.2.5 Source Molecular Corporation authorizes specific personnel to perform particular types of tests, to issue test reports, and to give opinions and interpretations and to operate particular types of equipment. Records are maintained of the relevant authorizations, competence, educational and professional qualifications, training, skills and experience of all technical personnel, including contracted personnel. This information is readily available and includes the date on which authorization and/or competence is confirmed.
- 5.2.6 Laboratory management is responsible for:
- 5.2.6.1 Defining the minimal level of qualification, experience, and skills necessary for all positions in the laboratory. Basic laboratory skills shall be considered.
 - 5.2.6.2 Ensuring that all technical laboratory staff have demonstrated capability in the activities for which they are responsible. Such demonstration is documented.
 - 5.2.6.3 Ensuring that the training of each member of the technical staff is kept up-to-date by the following:

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- 5.2.6.3.1 Evidence is on file that demonstrates that each employee has read, understood, and is using the latest version of the laboratory's in-house quality documentation that relates to his/her job responsibilities.
- 5.2.6.3.2 Training courses or workshops on specific equipment, analytical techniques, or laboratory procedures is documented.
- 5.2.6.3.3 Analyst training is considered up to date if an employee training file contains a certification that technical personnel have read, understood, and agreed to perform the most recent version of the test method and documentation of continued proficiency by at least one of the following once per year:
 - 5.2.6.3.3.1 Acceptable performance of a blind sample (single blind to the analyst). NOTE: successful analysis of a blind performance sample on a similar test method using the same technology would only require documentation for one of the test methods. Acceptable limits of blind performance sample is determined prior to analysis.
 - 5.2.6.3.3.2 An initial measurement system evaluation or another demonstration of capability.
 - 5.2.6.3.3.3 At least four consecutive laboratory control samples with acceptable levels of precision and accuracy. The laboratory will determine the acceptable limits for precision and accuracy prior to analysis.
 - 5.2.6.3.3.4 If 5.2.6.3.3.1 – 3 cannot be performed, analysis of authentic samples with results statistically indistinguishable from those obtained by another trained analyst.
- 5.2.6.3.4 Documenting all analytical and operational activities of the laboratory.
- 5.2.6.3.5 Supervising all personnel employed by the laboratory.
- 5.2.6.3.6 Ensuring that all sample acceptance criteria are verified and that samples are logged into the sample tracking system and properly labeled and stored.
- 5.2.6.3.7 Documenting the quality of all data reported by the laboratory.
- 5.2.7 Data integrity training is provided as a formal part of new employee orientation and is also provided on an annual basis for all current employees. Topics covered are documented in writing and provided to all trainees. Key topics covered during training include organizational mission and its relationship to the critical need for honesty and full disclosure in all analytical reporting, how and when to report data integrity issues, and record keeping. Training includes discussion regarding all data integrity procedures, data integrity training documentation, in-depth data monitoring and data integrity procedure documentation. Employees are informed that any infractions of the laboratory data integrity procedures will result in a detailed investigation that could lead to very serious consequences including immediate termination, debarment or civil/criminal prosecution. The initial data integrity training and the annual refresher training have a signature attendance sheet that demonstrates all staff have participated and understand their obligations related to data integrity. Senior managers acknowledge their support of these procedures by upholding the spirit and intent of Source Molecular Corporation's data integrity procedures, and effectively implementing the specific requirements of the procedures. Specific examples of breaches of ethical behavior are discussed, including improper data manipulations, adjustments of the instrument time clocks, and inappropriate changes in concentrations of standards. Data integrity training emphasizes the importance of proper written narration on the part of the analyst with respect to those cases where analytical data may be useful, but are in one sense or another partially deficient. The data integrity procedures includes a written ethics agreement.

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Responsibility

Laboratory Directors

References

Procedures

Training of Personnel (SOP Q-14)

Quality Policy Manual

5.3 Accommodation and Environmental Conditions

Policy

Source Molecular Corporation ensures that proper accommodation and environmental conditions are provided for the laboratory facilities.

Quality System Requirements

- 5.3.1 Source Molecular Corporation ensures those laboratory facility conditions such as energy sources, lighting and environmental conditions are adequate to facilitate the correct performance of the test. The technical requirements for accommodation and environmental conditions that can affect the results of tests and calibration are documented and are met before testing begins; this includes when testing occurs at sites other than the permanent facility.
- 5.3.2 Source Molecular Corporation monitors, controls and records environmental conditions where necessary to maintain quality of testing and calibration as required by the relevant specifications, methods and procedures or where they influence the quality of the results. Electrical supply, temperature, sound and vibration levels, biological sterility, dust, electromagnetic disturbances, radiation, and humidity as appropriate to the technical activities, are taken into consideration. Tests and calibration will be stopped when environmental conditions jeopardize the results of the tests. In instances where monitoring or control of any of the above mentioned items is specified in a test method or by regulation, Source Molecular Corporation meets and documents adherence to the laboratory facility requirements.
- 5.3.3 There is effective separation between work areas that are incompatible to prevent cross contamination.
- 5.3.4 Access to areas affecting the quality of the tests is controlled and such control is appropriate to the particular circumstances.
- 5.3.5 Good housekeeping measures are taken with special procedures as needed.
- 5.3.6 Work spaces are available to ensure an unencumbered work area. Work areas include:
 - 5.3.6.1 Access and entryways to the laboratory.
 - 5.3.6.2 Sample receipt area.
 - 5.3.6.3 Sample storage area.
 - 5.3.6.4 Chemical and waste storage area.
 - 5.3.6.5 Data handling and storage areas.
- 5.3.7 Floors and work surfaces are non-absorbent and easy to clean and disinfect. Work surfaces are adequately sealed. Source Molecular Corporation provides sufficient storage space, and the laboratory is clean and free from dust accumulation. Plants, food, and drink are prohibited from the laboratory work area.

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Responsibility

President

References

Procedures

Environmental Monitoring (SOP Q-2)

Dishwashing (SOP Q-6)

Autoclaving (SOP Q-13)

Policy

Source Molecular Corporation ensures that the test methods are validated and implemented accordingly.

Quality System Requirements

- 5.4.1 General: Source Molecular Corporation uses appropriate methods and procedures within its scope. Methods and procedures include handling, transport, storage and preparation of samples, and where appropriate, an estimation of the measurement uncertainty as well as statistical techniques for analysis of test data. Instructions on the use and operation of all relevant equipment, and on the handling and preparation of samples are provided where the absence of such instructions could jeopardize the test results. Instructions, standards, manuals and reference data relevant to the work of the laboratory is kept up to date and made readily available to personnel as necessary. Deviation from test and/or calibration methods are implemented when such deviations are documented, technically justified, authorized and accepted by the client.
- 5.4.1.1 Standard Operating Procedures (SOP's): Source Molecular Corporation maintains SOP's that accurately reflect all phases of current laboratory activities such as assessing data integrity, corrective actions, handling customer complaints, and all test methods.
- 5.4.1.1.1 These documents may include equipment manuals provided by the manufacturer or internally written documents with adequate detail to allow someone similarly qualified, other than the analyst, to reproduce the procedures used to generate the test result.
- 5.4.1.1.2 Test methods may include copies of published methods, provided any changes or selected options in the methods are documented and included in the methods manual.
- 5.4.1.1.3 Copies of all SOP's are accessible to all personnel.
- 5.4.1.1.4 SOP's are organized.
- 5.4.1.1.5 Each SOP clearly indicate the effective date of the document, the revision number, and the signatures of the approving authority.
- 5.4.1.1.6 The documents specified in 1 and 2 that contain sufficient information to perform tests do not need to be supplemented or rewritten as internal procedures, if the documents are written in a way that they can be used as written. Any changes, including the use of a selected option is documented and included in Source Molecular Corporation's methods manual.
- 5.4.1.2 Laboratory Method Manuals:
- 5.4.1.2.1 Source Molecular Corporation has and maintains an in-house methods manual for each accredited analyte or test method.

Quality Policy Manual

5.4 Test Methods and Method Validation

- 5.4.1.2.2 This manual may consist of copies of published or referenced test methods or SOP's that have been written by the laboratory. In cases where modifications to the published method have been made by the laboratory or where the referenced test method is ambiguous or provides insufficient detail, these changes or clarifications are clearly described. Each test method includes or references where applicable:
- 5.4.1.2.2.1 Identificaiton of the test method.
 - 5.4.1.2.2.2 Applicable matrix or matrices.
 - 5.4.1.2.2.3 Detection limit.
 - 5.4.1.2.2.4 Scope and application, including components to be analyzed.
 - 5.4.1.2.2.5 Summary of the test method.
 - 5.4.1.2.2.6 Definitions.
 - 5.4.1.2.2.7 Interferences.
 - 5.4.1.2.2.8 Safety.
 - 5.4.1.2.2.9 Equipment and supplies.
 - 5.4.1.2.2.10 Reagents and standards.
 - 5.4.1.2.2.11 Sample collection, preservation, shipment and storage.
 - 5.4.1.2.2.12 Quality control.
 - 5.4.1.2.2.13 Calibration and standardization.
 - 5.4.1.2.2.14 Procedure.
 - 5.4.1.2.2.15 Data analysis and calculations.
 - 5.4.1.2.2.16 Method performance.
 - 5.4.1.2.2.17 Pollution prevention.
 - 5.4.1.2.2.18 Data assessment and acceptance criteria for quality control measures.
 - 5.4.1.2.2.19 Corrective actions for out-of-control data.
 - 5.4.1.2.2.20 Contingencies for handling out-of-control or unacceptable data.
 - 5.4.1.2.2.21 Waste management.
 - 5.4.1.2.2.22 References.
 - 5.4.1.2.2.23 Any tables, diagrams, flowcharts, and validation data.
- 5.4.2 Selection of Methods: Source Molecular Corporation uses methods for environmental testing which meet the needs of the client and which are appropriate for the environmental tests it undertakes.
- 5.4.2.1 Sources of Methods:
 - 5.4.2.1.1 Methods published in international, regional or national standards are preferably used. Source Molecular Corporation ensures the use of latest valid edition of standards, unless it is not appropriate or possible to do so. When necessary, standards are supplemented with additional details to ensure consistent application
 - 5.4.2.1.2 When the use of specific methods for a sample analysis is mandated or requested, only those methods are used.

Method Validation

- 5.4.2.1.3 When the client does not specify the method to be used or where methods are employed that are not required, the methods are fully documented and validated and available to the client and other recipients of the relevant reports. Source Molecular Corporation shall select appropriate published methods when client has not specified a method. Laboratory developed methods and methods adopted by the laboratory are used if appropriate and are validated. Client is informed of method chosen.
- 5.4.2.1.4 Client is informed if the standard proposed by the client is considered to be inappropriate or out of date.
- 5.4.2.2 Source Molecular Corporation confirms that it can perform standard methods before introducing the tests. If standard method changes, confirmation is repeated.
- 5.4.2.2.1 Prior to acceptance and institution of any method, satisfactory demonstration of method capability is demonstrated using clean quality matrix sample, e.g. drinking water, solids, biological tissue or air. For analytes which do not lend themselves to spiking, the demonstration of capability may be performed using quality control samples.
- 5.4.2.2.2 Thereafter, continuing demonstration of method performance, as per the quality control requirements, such as laboratory control samples, is required.
- 5.4.2.2.3 In cases where the laboratory analyzes samples using a method that has been in use by the laboratory before July 1999, and there have been no significant changes in instrument type, personnel or method, the continuing demonstration of method performance and the analyst's documentation of continued proficiency is acceptable. The laboratory shall have records on file to demonstrate that a demonstration of capability is not required.
- 5.4.2.2.4 In all cases, the appropriate forms such as the Certification Statement are completed and retained by the laboratory and available upon request. All associated supporting data necessary to reproduce the analytical results summarized in the Certification Statement are retained by the laboratory.
- 5.4.2.2.5 A demonstration of capability will be completed each time there is a change in instrument type, personnel, or method.
- 5.4.2.2.6 Source Molecular Corporation does not use specialized work cells.
- 5.4.3 Laboratory-developed Methods
- The introduction of methods developed by the lab is a planned activity and development is assigned to qualified personnel equipped with adequate resources.
 - Plans shall be updated as development proceeds and communication among personnel involved will be ensured.
- 5.4.4 Non-standard Methods
- Non-standard methods are subject to agreement with the client, and include specification of client's requirements and purpose of the test. Method developed shall be validated before use.

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5.4.5 Validation of Methods

5.4.5.1 Validation is confirmation by examination and the provision of objective evidence that the particular requirements for a specific intended use are fulfilled.

5.4.5.2 Non-standard and laboratory-designed/developed methods, standard methods used outside their intended scope, and amplifications and modifications of standard methods are validated to confirm that they are fit for the intended use. The validation is as extensive as is necessary to meet the needs of the given application or field of application. 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. The minimum requirements are the initial test method evaluation requirements.

5.4.5.3 The range and accuracy of the values obtainable from validated methods shall be relevant to the client's needs.

5.4.6 Estimation of uncertainty of measurement

5.4.6.1 Source Molecular Corporation has and applies procedures to estimate the uncertainty of measurement. When the nature of the test method precludes rigorous, metrologically and statistically valid calculation of uncertainty of measurement, the laboratory shall attempt to identify all the components of uncertainty and make a reasonable estimation, and shall ensure that the form of reporting of the result does not give a wrong impression of the uncertainty. Reasonable estimation shall be based on knowledge of the performance of the method and on the measurement scope and shall make use of, for example, previous experience and validation data. 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 will simply follow the test method and reporting instructions.

5.4.6.2 All uncertainty components which are of importance in a given situation shall be taken into account using appropriate methods of analysis when estimating uncertainty of measurement.

5.4.7 Control of data:

5.4.7.1 Calculations and data transfers are subject to appropriate checks in a systematic manner

5.4.7.1.1 Source Molecular Corporation as established SOP's to ensure that the reported data are free from transcription and calculation errors.

5.4.7.1.2 Source Molecular Corporation as established SOP's to ensure that all quality control measures are reviewed and evaluated before data are reported.

5.4.7.1.3 Source Molecular Corporation as established SOP's addressing manual calculations including integrations.

5.4.7.2 When computers, automated equipment, or microprocessors are used for the acquisition, processing, recording, storage, or retrieval of environmental test data, the laboratory ensures that:

5.4.7.2.1 Computer software developed by the user is documented in sufficient detail and is suitably validated as being adequate for use.

5.4.7.2.2 Procedures are established and implemented for protecting the data, including integrity and confidentiality of data entry and collection, data storage, data transmission, and data processing.

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5.4.7.2.3 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 environmental test data.

5.4.7.2.4 Appropriate procedures are implemented for maintenance of security of data including the prevention of unauthorized access to, and the unauthorized amendment of, computer records.

5.4.7.2.5 Commercial off-the-shelf software in general use within their designed application range is considered to be sufficiently validated. Laboratory software configuration or modifications are validated as above.

5.4.8 Method Evaluation:

5.4.8.1 Source Molecular Corporation demonstrates proficiency with a test method prior to first use. This is achieved by comparison to a method already approved for use in the laboratory, or by analyzing a minimum of ten spiked samples whose quality system matrix is representative of those normally submitted to the laboratory, or by analyzing and passing one proficiency test series provided by an approved proficiency sample provider. The laboratory maintains this documentation as long as the method is in use and for at least 5 years past the date of last use.

5.4.8.2 Source Molecular Corporation participates in the Proficiency Test programs identified by NELAP. The results of these analyses are used to evaluate the ability of the laboratory to produce acceptable data.

Responsibility

Laboratory Director

References

Procedures

Thermometer Calibration (SOP Q-8)

Test and Calibration Methods and Method Validation ()

Policy

Source Molecular Corporation ensures the proper equipment is available and is suitable for the delivery of intended service.

Quality System Requirements

- 5.5.1 Lab is furnished with all items of equipment required for correct performance of testing. Equipment outside permanent control shall be controlled to meet all standards
- 5.5.2 Equipment and software meet the accuracy necessary for the testing and comply with specifications relevant to environmental tests concerned. Equipment shall be calibrated or checked to establish that it meets the specification requirements and complies with relevant standards before being put into service.
 - 5.5.2.1 Support Equipment:
 - 5.5.2.1.1 All support equipment is maintained in proper working order. The records of all repair and maintenance activities including service calls are kept on file.
 - 5.5.2.1.2 All support equipment is calibrated or verified annually, using NIST traceable references when available, over the entire range of use. The results of such calibration or verification shall be within the specifications required of the application for which this equipment is used or:
 - 5.5.2.1.2.1 The equipment shall be removed from service until repaired or
 - 5.5.2.1.2.2 The laboratory shall maintain records of established correction factors to correct all measurements.
 - 5.5.2.1.3 Raw data records are retained to document equipment performance.
 - 5.5.2.1.4 Prior to use on each working day, balances, ovens, refrigerators, freezers, and water baths are checked in the expected use range, with NIST traceable references where commercially available. The acceptability for use or continued use shall be according to the needs of the analysis or application for which the equipment is being used.
 - 5.5.2.2 Instrument Calibration:
 - 5.5.2.2.1 Initial instrument calibration:
 - 5.5.2.2.1.1 The details of the initial instrument calibration procedures including calculations, integrations, acceptance criteria and associated statistics are included or referenced in the test method SOP. When initial instrument calibration procedures are referenced in the test method, then the referenced material will be retained by the laboratory and be available for review.
 - 5.5.2.2.1.2 Sufficient raw data records will be retained to permit reconstruction of the initial instrument calibration, e.g., calibration date, test method, instrument, analysis date, each analyte name, analyst's initials, concentration and response, calibration curve or response factor, or unique equation or coefficient used to reduce instrument responses to concentration.

- 5.5.2.2.1.3 Sample results are quantitated from the initial instrument calibration and may not be quantitated from any continuing instrument calibration verification unless otherwise required by regulation, method, or program.
- 5.5.2.2.1.4 All initial instrument calibrations will be verified with a standard obtained from a second manufacturer or lot if the lot can be demonstrated from the manufacturer as prepared independently from other lots. Traceability shall be to a national standard, when commercially available.
- 5.5.2.2.1.5 Criteria for the acceptance of an initial instrument calibration will be established, e.g., correlation coefficient or relative percent difference. The criteria used will be appropriate to the calibration technique employed.
- 5.5.2.2.1.6 The lowest calibration standard shall be the lowest concentration for which quantitative data are to be reported. Any data reported below the lower limit of quantitation will be considered to have an increased quantitative uncertainty and shall be reported using defined qualifiers or flags or explained in the case narrative.
- 5.5.2.2.1.7 The highest calibration standard shall be the highest concentration for which quantitative data are to be reported. Any data reported above this highest standard will be considered to have an increased quantitative uncertainty and shall be reported using defined qualifiers or explained in the case narrative.
- 5.5.2.2.1.8 Measured concentrations outside the working range shall be reported as having less certainty and shall be reported using defined qualifiers or flags or explained in the case narrative. The lowest calibration standard must be above the limit of detection. Noted exception: the following shall occur for instrument technology with validated techniques from manufacturers or methods employing standardization with a zero point and a single point calibration standard:
- 5.5.2.2.1.8.1 Prior to the analysis of samples the zero point and single point calibration will be analyzed and the linear range of the instrument will be established by analyzing a series of standards, one of which must be at the lowest quantitation level. Sample results within the established linear range will not require data qualifier flags.
- 5.5.2.2.1.8.2 Zero point and single-point calibration standard must be analyzed with each analytical batch.
- 5.5.2.2.1.8.3 A standard corresponding to the limit of quantitation must be analyzed with each analytical batch and must meet established acceptance criteria.
- 5.5.2.2.1.8.4 The linearity is verified at a frequency established by the method and/or the manufacturer.
- 5.5.2.2.1.9 If the initial instrument calibration results are outside established acceptance criteria, corrective actions will be performed and all associated samples will be reanalyzed. If reanalysis of the samples is not possible, data associated with an unacceptable initial instrument calibration shall be reported with appropriate data qualifiers.

- 5.5.2.2.1.10 If a reference or mandated method does not specify the number of calibration standards, the minimum number is two, one of which must be at the limit of quantitation, not including blanks or a zero standard with the noted exception of instrument technology for which it has been established by methodologies and procedures that a zero and a single point standard are appropriate for calibrations. The laboratory will have a SOP for determining the number of points for establishing the initial instrument calibration.
- 5.5.3 Equipment is operated by authorized personnel. Up to date instructions for the equipment use and maintenance are readily available. All equipment is properly maintained, inspected, and cleaned. Maintenance procedures are documented.
- 5.5.4 Equipment and software are uniquely identified.
- 5.5.5 Source Molecular Corporation maintains records for each major item of equipment significant to the tests performed, including:
- 5.5.5.1 Identity of item of equipment
- 5.5.5.2 Manufacturer's name, type, identification and serial number or other unique identification.
- 5.5.5.3 Checks that equipment complies with the specification.
- 5.5.5.4 Current location, where appropriate.
- 5.5.5.5 Manufacturer's instructions, if available, or reference to their location.
- 5.5.5.6 Dates, results and copies of reports and certificates of calibration, adjustments, acceptance criteria, and due date of next calibration
- 5.5.5.7 Maintenance plan, where appropriate, and maintenance carried out to date' documentation on all routine and non-routine maintenance activities and reference material verifications.
- 5.5.5.8 Damage, malfunction, modification or repair to equipment.
- 5.5.5.9 Date received and date placed in service, if available.
- 5.5.5.10 Condition when received, if available.
- 5.5.6 Procedures are established for safe handling, transport, storage, use and planned maintenance of the measuring equipment.
- 5.5.7 Overloaded or mishandled equipment that gives suspect results are taken out of service, isolated and labeled accordingly until it has been repaired and calibrated. Effect of the defect or departure from previous limits on previous testing and/or calibration are examined and "Control of nonconforming work" procedures are initiated.
- 5.5.8 Equipment shall be labeled, coded or otherwise identified to indicate status of calibration, including date calibrated, and date or expiration criteria when recalibration is due.
- 5.5.9 If equipment goes outside the control of the lab, it shall be proven that the function and calibration status are satisfactory before being returned to service.
- 5.5.10 When an initial instrument calibration is not performed on the day of analysis, the validity of the initial calibration is verified prior to sample analyses by continuing instrument calibration verification with each analytical batch. The following items are essential elements of continuing instrument verification:

- 5.5.10.1 The details of the continuing instrument calibration procedure, calculations, and associated statistics are included or referenced in the test method SOP.
- 5.5.10.2 Instrument calibration verification is performed:
 - 5.5.10.2.1 At the beginning and end of each analytical batch (except, if an internal standard is used, only one verification is performed at the beginning of the analytical batch).
 - 5.5.10.2.2 Whenever it is expected that the analytical system may be out of calibration or might not meet the verification acceptance criteria.
 - 5.5.10.2.3 If the time period for calibration or the most previous calibration verification has expired.
 - 5.5.10.2.4 For analytical systems that contain a calibration verification requirement.
- 5.5.10.3 Sufficient raw data records are retained to permit reconstruction of the continuing instrument calibration verification, e.g. test method, instrument, analysis date, each analyte name, concentration and response, calibration curve or response factor, or unique equations or coefficients used to convert instrument responses into concentrations. Continuing calibration verification records explicitly connect the continuing verification data to the initial instrument calibration.
- 5.5.10.4 Criteria for the acceptance of a continuing instrument calibration verification is established. If the continuing instrument calibration verification results obtained are outside established acceptance criteria, corrective actions are performed. If routine corrective action procedures fail to produce a second consecutive, immediate, calibration verification within acceptance criteria, then either the laboratory will demonstrate acceptable performance after corrective action with two consecutive calibration verifications, or a new initial instrument calibration will be performed. If the laboratory has not verified calibration, sample analyses will not occur until the analytical system is calibrated or calibration verified. If samples are analyzed using a system on which the calibration has not yet been verified, the results will be flagged. Data associated with an unacceptable calibration verification may be fully useable under the following special conditions:
 - 5.5.10.4.1 When the acceptance criteria for the continuing calibration verification are exceeded high, i.e. high bias, and there are associated samples that are non-detects, then those non-detects may be reported. Otherwise the samples affected by the unacceptable calibration verification shall be reanalyzed after a new calibration curve has been established, evaluated, and accepted.
 - 5.5.10.4.2 When the acceptance criteria for the continuing calibration verification are exceeded low, i.e. low bias, those sample results may be reported if they exceed a maximum regulatory limit/decision level. Otherwise the samples affected by the unacceptable verification shall be reanalyzed after a new calibration curve has been established, evaluated, and accepted.
- 5.5.11 Where calibrations give rise to a set of correction factors, Source Molecular Corporation provides procedures to ensure that copies are updated correctly. (4.5)
- 5.5.12 Equipment and software is safeguarded from adjustments that would invalidate the testing and calibration results. (4.12)

5.5.13 Temperature Measuring Devices such as liquid-in-glass thermometers, thermocouples, and platinum resistance thermometers used in incubators, autoclaves and other equipment is the appropriate quality to meet specifications in the test method. The graduation of the temperature measuring devices is appropriate for the required accuracy of measurement, and they are calibrated to national or international standards for temperature, at least annually. (5.6.2.2.2)

5.5.14 Autoclaves:

5.5.14.1 The performance of each autoclave is initially evaluated by establishing its functional properties and performance, for example heat distribution characteristics with respect to typical uses. Autoclaves meet specified temperature tolerances. Pressure cookers are not used for sterilization of growth media.

5.5.14.2 Demonstration of sterilization temperature is provided by use of a maximum registering thermometer with every cycle. Appropriate biological indicators are used once per month to determine effective sterilization. Temperature sensitive tape is used with the contents of each autoclave run to indicate that the autoclave contents have been processed.

5.5.14.3 Records of autoclave operations are maintained for every cycle. Records include: date, contents, maximum temperature reached, pressure, time in sterilization mode, total run time (may be recorded as time in and time out) and analyst's initials.

5.5.14.4 Autoclave maintenance, either internally or by service contract, is performed annually and includes a pressure check and calibration of temperature device. Records of the maintenance is maintained in equipment logs.

5.5.14.5 The autoclave mechanical timing device is checked quarterly against a stopwatch and the actual time elapsed documented.

Responsibility

Laboratory Directors

Calibration and Maintenance of Laboratory equipment

pH meters - All pH meters are calibrated within + 0.1 units using three point calibration (4.0, 7.0, 10.0) prior to each use and recorded in a log book. All pH calibration buffers (NIST Traceable) are aliquotted and used only once and stocks are discarded upon expiration. Electrodes are maintained according to manufacturer's instructions.

Balances - All balances are calibrated monthly using ASTM (NIST traceable) type weights at three (3) different points. In addition, professional calibration of all balances occurs at least once annually.

Incubators – All incubators are maintained at their desired temperature + 0.5 °C or +0.2 °C, depending on application. Incubator temperatures are monitored using bulb thermometers immersed in glycerol, which are calibrated by a NIST traceable thermometer. Temperatures are recorded daily on log sheets. Any problems are noted on the troubleshooting log and brought to the attention of T. M. Scott. Documentation must be provided as to steps taken to correct problems as they arise. The problem log is located in the QC notebook.

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Autoclave - Each autoclave cycle is recorded in a log book that indicates the date, contents, sterilization time, temperature, and analyst's initials. A maximum temperature registering thermometer is included on each run and is recorded. Sterilization efficiency is monitored monthly using spores of *Bacillus stearothermophilus* as a control.

Sterilization procedures - All items are sterilized in the autoclave at 121°C for a minimum of 15 minutes. Biohazardous wastes are sterilized for a minimum of 30 minutes.

Refrigerators - All refrigerators/freezers are monitored to maintain a temperature of 1-8 °C by a bulb thermometer immersed in glycerol.

Procedures

pH Meter Calibration (SOP Q-3)
Thermometer Calibration (SOP Q-8)
Balance Calibration (SOP Q-9)
Microscope Calibration (SOP Q-10)
Equipment Maintenance Log

Policy

Source Molecular Corporation ensures that all equipment used for tests and/or calibration are calibrated and are traceable to National and/or International standards.

Quality System Requirements

5.6.1 General

5.6.1.1 All equipment used for testing, including equipment for subsidiary measurements and having significant effect on the accuracy or validity of the results of the test are calibrated before being put into service and on a continuing basis. This includes balances, thermometers, and control standards. Such a program shall include a system for selecting, using, calibrating, checking, controlling and maintaining measurement standards, reference materials used as measurement standards, and measuring and test equipment used to perform environmental tests.

5.6.2 Testing Laboratories:

5.6.2.1 Source Molecular Corporation ensures that the equipment used can provide the uncertainty of measurement needed.

5.6.2.1.1 The overall program of calibration and/or verification and validation of equipment is designed and operated so as to ensure that measurements made by the laboratory are traceable to national standards of measurement.

5.6.2.2 Where traceability of measurements to SI units is not possible or not relevant, the same requirements for traceability to, for example, certified reference materials, agreed methods and/or consensus standards, are in effect. The laboratory provides satisfactory evidence of correlation of results.

5.6.3 Reference Standards and Reference Materials:

5.6.3.1 Reference standards: the laboratory has a program and procedure for the calibration of its reference standards. Reference standards are calibrated by a body that can provide traceability as described in 5.6.2.1. Such reference standards of measurement held by the laboratory (such as class S or equivalent weights or traceable thermometers) 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. Reference standards are calibrated before and after any adjustment. Where commercially available, this traceability is to a national standard of measurement.

5.6.3.2 Reference materials: Reference materials are, where commercially available, traceable to SI units of measurement, or to certified reference materials. Where possible, traceability is to national or international standards of measurement, or to national or international standard reference materials. Internal reference materials are checked as far as is technically and economically practicable.

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

5.6.3.4 Transport and storage: the laboratory has procedures for 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.

5.6.4 Source Molecular Corporation, has documented procedures for the purchase, reception, and storage of consumable materials used for the technical operations of the laboratory.

- 5.6.4.1 The laboratory retains records for all standards, reagents, reference materials, and media including the manufacturer/vendor, the manufacturer's Certificate of Analysis or purity, if supplied, the date of receipt, recommended storage conditions, and an expiration date after which the material shall not be used unless its reliability is verified by the laboratory.
 - 5.6.4.2 Original containers, such as provided by the manufacturer or vendor, are labeled with an expiration date.
 - 5.6.4.3 Records are maintained on standard and reference material preparation. These records indicate traceability to purchased stocks or neat compounds, reference to the method of preparation, date of preparation, expiration date, and preparer's initials.
 - 5.6.4.4 All containers of prepared, standards, and reference materials will bear a unique identifier and expiration date and be linked to the documentation requirements in 5.6.4.3.
 - 5.6.4.5 Procedures are in place to ensure prepared reagents meet the requirements of the test method. The source of reagents complies with 5.9.2.1.6 and D.1.4.2.
 - 5.6.4.6 All containers of prepared reagents bear a preparation date. An expiration date is defined on the container or documented elsewhere as indicated in the laboratory's quality manual or SOP.
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Responsibility

Laboratory Directors

References

Procedures

- pH Meter Calibration (SOP Q-3)
- Thermometer calibration (SOP Q-8)
- Balance Calibration (SOP Q-9)
- Microscope Calibration (SOP Q-10)
- Reference Standards and Materials (SOP Q-20)
- Calibration Logs located at each instrument and filed in calibration log notebook

Quality Policy Manual

5.7 Sampling

Policy

Source Molecular Corporation performs sampling under the current scope through set sampling plans and procedures.

Quality System Requirements

- 5.7.1 Source Molecular Corporation has a sampling plan and procedures for sampling when it carries out sampling of substances, materials, or products for subsequent environmental testing. The sampling plan as well as the sampling procedure is made available at the location where the sampling is undertaken. Sampling plans are, whenever reasonable, based on appropriate statistical methods. The sampling process addresses the factors to be controlled to ensure the validity of the environmental test results. Where sampling (as in obtaining sample aliquots from a submitted sample) is carried out as part of the test method, the laboratory uses documented procedures and appropriate techniques to obtain representative subsamples.
- 5.7.2 Where the client requires deviations, additions, or exclusions from the documented sampling procedure, these are recorded in detail with the appropriate sampling data and are included in all documents containing environmental test and/or calibration results, and are communicated to the appropriate personnel.
- 5.7.3 The laboratory has procedures for recording relevant data and operations relating to sampling that forms part of the environmental testing that is undertaken. These records include the sampling procedure used, the identification of the sampler, environmental conditions (if relevant) and diagrams or other equivalent means to identify the sampling location as necessary and, if appropriate, the statistics the sampling procedures are based upon.
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Responsibility

Laboratory Directors

References

Procedures

Field Quality Control Requirements (SOP FS-1)
Field Temperature (SOP FS-2)
Field pH (SOP FS-3)
Wastewater and Sludge Sampling (SOP FS-4)
Surface Water Sampling (SOP FS-5)

Policy

Source Molecular Corporation ensures that samples are controlled through handling, storage, packaging, preservation, and delivery in such a manner that product integrity is maintained.

Quality System Requirements

- 5.8.1 Source Molecular Corporation has procedures for transportation, receipt, handling, protection, storage, retention and/or disposal of samples, including all provisions necessary to protect sample integrity and the interests of the laboratory and the client.
- 5.8.2 Samples are identified and identity is retained throughout life of the sample in the lab. Samples are identified to ensure they cannot be confused physically or when referred to in records and other documents. Sample identification accommodates sub-division of groups and transfer within and from the laboratory.
 - 5.8.2.1 The laboratory has a documented system for uniquely identifying the samples to be tested, to ensure that there can be no confusion regarding the identity of such samples at any time. This system includes identification for all samples, subsamples, and subsequent extracts and/or digestates. The laboratory assigns a unique identification code to each sample container received in the laboratory.
 - 5.8.2.2 The laboratory code maintains an unequivocal link with the unique field ID code assigned each container.
 - 5.8.2.3 The laboratory ID code is placed on the sample container as a durable label.
 - 5.8.2.4 The laboratory ID code is entered in to the laboratory records and is the link that associates the sample with related laboratory activities such as sample preparation.
 - 5.8.2.5 The laboratory ID code may be the same as the field ID code.
- 5.8.3 Upon receipt of a sample, the condition, including abnormalities or departures from normal or specified conditions are recorded. When suitability is in doubt, or when a sample does not conform to the description provided, or the environmental test required is not specified in sufficient detail, the client is consulted for further instructions before proceeding and discussions are recorded.
 - 5.8.3.1 Sample receipt protocols:
 - 5.8.3.1.1 All items specified in 5.8.3.2 shall be checked.
 - 5.8.3.1.1.1 All samples which require thermal preservation shall be considered acceptable if the arrival temperature is either within 2 C of the required temperature or the method specified range. For samples with a specified temperature of 4 C, samples with a temperature ranging from just above the freezing temperature of water to 6 C shall be acceptable. Samples that are hand delivered to the laboratory on the same day that they are collected may not meet these criteria. In these cases, the samples shall be considered acceptable if there is evidence that the chilling process has begun such as arrival on ice.

- 5.8.3.1.1.2 The laboratory has implemented procedures for checking chemical preservation using readily available techniques, such as pH or chlorine, prior to or during sample preparation or analysis.
- 5.8.3.1.1.3 Microbiological samples from chlorinated water systems do not require an additional chlorine residual check in the laboratory if the following conditions are met:
 - 5.8.3.1.1.3.1 Sufficient sodium thiosulfate is added to each container to neutralize at minimum 5 mg/L of chlorine for drinking water and 15 mg/L of chlorine for wastewater samples.
 - 5.8.3.1.1.3.2 One container from each batch of laboratory prepared containers or lot of purchased ready-to-use containers is checked to ensure efficacy of the sodium thiosulfate to 5 mg/L of chlorine or 15 mg/L of chlorine as appropriate and the check is documented.
 - 5.8.3.1.1.3.3 Chlorine residual is checked in the field and actual concentration is documented with sample submission.
- 5.8.3.1.2 The results of all checks is recorded.
- 5.8.3.1.3 If the sample does not meet the sample receipt acceptance criteria listed in this standard, the laboratory shall either:
 - 5.8.3.1.3.1 Retain correspondence and/or records of conversations concerning the final disposition of rejected samples, or
 - 5.8.3.1.3.2 Fully document any decision to proceed with the analysis of samples not meeting acceptance criteria.
 - 5.8.3.1.3.2.1 The condition of these samples shall, at a minimum, be noted on the chain of custody or transmittal form and laboratory receipt documents.
 - 5.8.3.1.3.2.2 The analysis data shall be appropriately “qualified” on the final report.
- 5.8.3.1.4 Source Molecular Corporation utilizes a permanent chronological record to document receipt of all sample containers.
 - 5.8.3.1.4.1 This sample receipt log records the following:
 - 5.8.3.1.4.1.1 Client/project name.
 - 5.8.3.1.4.1.2 Date and time of laboratory receipt.
 - 5.8.3.1.4.1.3 Unique laboratory ID code (5.8.2).
 - 5.8.3.1.4.1.4 Signature or initials of the person making the entries.
 - 5.8.3.1.4.2 During the log-in process, the following information is unequivocally linked to the log record or included as part of the log. If such information is recorded/documentated elsewhere, the records are part of the laboratory’s permanent records, easily retrievable upon request and readily available to individuals who will process the sample.
 - 5.8.3.1.4.2.1 The field ID code which identifies each container is linked to the laboratory ID code in the sample receipt log.
 - 5.8.3.1.4.2.2 The date and time of sample collection is linked to the sample container and to the date and time of receipt in the laboratory.
 - 5.8.3.1.4.2.3 The requested analyses, including applicable approved test method numbers, are linked to the laboratory ID code.

- 5.8.3.1.4.2.4 Any comments resulting from inspection for sample rejection are linked to the laboratory code.
- 5.8.3.1.5 All documentation, such as memos or transmittal forms, that is transmitted to the laboratory by the sample transmitter are retained.
- 5.8.3.1.6 A complete chain of custody record form is maintained.
- 5.8.3.2 Sample acceptance policy: the laboratory has a written sample acceptance policy that clearly outlines the circumstances under which samples shall be accepted or rejected. Data from any samples which do not meet the following criteria are flagged in an unambiguous manner clearly defining the nature and substance of the variation. This sample acceptance policy will be made available to sample collection personnel and shall include the following:
 - 5.8.3.2.1 Proper, full, and complete documentation, which shall include sample identification, the location, date, and time of collection, collector's name, preservation type, sample type, and any special remarks concerning the sample.
 - 5.8.3.2.2 Proper sample labeling to include unique identification and a labeling system for the samples with requirements concerning the durability of the labels (water resistant) and the use of indelible ink.
 - 5.8.3.2.3 Use of appropriate sample containers.
 - 5.8.3.2.4 Adherence to specified holding times.
 - 5.8.3.2.5 Adequate sample volume. Sufficient sample volume must be available to perform the necessary tests.
 - 5.8.3.2.6 Procedures to be used when samples show signs of damage, contamination, or inadequate preservation.
- 5.8.4 Source Molecular Corporation maintains procedures and facilities to avoid deterioration, contamination, loss or damage to sample during storage, handling, preparation, and testing. Handling instructions provided with the item are followed. Environmental conditions used for storage and conditioning of the items is maintained, monitored and recorded when necessary. Samples or portions thereof are secured and stored properly to protect the integrity of the sample or portions concerned when necessary.
 - 5.8.4.1 Samples are stored according to the conditions specified by preservation protocols:
 - 5.8.4.1.1 Samples that require thermal preservation are stored under refrigeration which is +/- 2 C of the specified preservation temperature unless method specific criteria exist. For samples with a specified storage temperature of 4 C, storage at a temperature from 1 C to 6 C shall be acceptable.
 - 5.8.4.1.2 Samples shall be stored away from all standards, reagents, food, and other potentially contaminating sources. Samples shall be stored in such a manner to prevent cross contamination.
 - 5.8.4.2 Sample fractions, extracts, leachates, and other sample preparation products shall be stored according to 5.8.4.1 or according to specifications in the test method.

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5.8 Handling of Samples

5.8.4.2.1 The laboratory has SOP's for the disposal of samples, digestates, leachates, and extracts or other sample preparation products.

Responsibility

Laboratory Manager

References

Procedures

Receipt of Samples (SOP Q-4)

Quality Policy Manual

5.9 Assuring the Quality of Test Results

Policy

Source Molecular Corporation ensures the quality of test and calibration results is maintained.

Quality System Requirements

- 5.9.1 Quality control procedures exist for monitoring validity environmental tests undertaken. Resulting data is recorded to be able to detect trends using statistical techniques when practiceable. The monitoring will be planned and reviewed and may include:
- 5.9.1.1 Regular use of certified reference materials and/or internal quality control using secondary reference materials.
 - 5.9.1.2 Participation in inter-laboratory comparison or proficiency testing programs.
 - 5.9.1.3 Replicate tests using same or different methods.
 - 5.9.1.4 Retesting of retained items.
 - 5.9.1.5 Correlation of results for different characteristics of a sample.
- 5.9.2 Essential quality control procedures: the standards for any given test type shall assure that the applicable principles are addressed:
- 5.9.2.1 Detailed protocols are in place to monitor the following quality controls:
 - 5.9.2.1.1 Positive and negative controls to monitor tests such as blanks, spikes, reference toxicants.
 - 5.9.2.1.2 Tests to define the variability and/or repeatability of the laboratory results such as replicates.
 - 5.9.2.1.3 Measures to assure the accuracy of the test method including calibration and/or continuing calibrations, use of certified reference materials, proficiency test samples, or other measures.
 - 5.9.2.1.4 Measures to evaluate test method capability, such as limit of detection and limit of quantitation or range of applicability such as linearity.
 - 5.9.2.1.5 Selection of appropriate formulae to reduce raw data to final results such as regression analysis, comparison to internal/external standard calculations, and statistical analyses.
 - 5.9.2.1.6 Selection and use of reagents and standards of appropriate quality.
 - 5.9.2.1.7 Measures to assure the selectivity of the test for its intended purpose.
 - 5.9.2.1.8 Measures to assure constant and consistent test conditions, both instrumental and environmental, where required by the test method such as temperature, humidity, light, or specific instrument conditions.
 - 5.9.2.2 All quality control measures are assessed and evaluated on an on-going basis, and quality control acceptance criteria are used to determine the usability of the data.
 - 5.9.2.3 The laboratory has procedures for the development of acceptance/rejection criteria where no method or regulatory criteria exist. (See 5.8.3.2)

Quality Policy Manual**5.9 Assuring the Quality of Test Results**

- 5.9.2.4 The quality control protocols specified by the laboratory's method manual (5.4.1.2) is followed. The laboratory ensures that the essential standards outlined in mandated methods or regulations are incorporated into method manuals.
- 5.9.3 Sterility checks and blanks: The laboratory demonstrates that the filtration equipment and filters, sample containers, media and reagents have not been contaminated through improper handling or preparation, inadequate sterilization, or environmental exposure.
- 5.9.3.1 A sterility blank is analyzed for each lot of pre-prepared, ready-to-use medium and for each batch of medium prepared in the laboratory. This is done prior to first use of the medium.
- 5.9.3.2 For filtration technique, the laboratory conducts one beginning and one ending sterility check for each laboratory sterilization filtration unit used in a filtration series. The filtration series may include single or multiple filtration units, which have been sterilized prior to beginning the series. For pre-sterilized single use funnels a sterility check is performed on one funnel per lot. The filtration series is considered ended when more than 30 minutes elapses between successive filtrations. During a filtration series, filter funnels are rinsed with three 20-30 ml portions of sterile rinse water after each sample filtration. In addition, the laboratory inserts a sterility blank after every 10 samples or sanitize filtration units by UV light after each sample filtration.
- 5.9.3.3 For pour plate technique, sterility blanks of the medium are made by pouring, at a minimum, one uninoculated plate for each lot of pre-prepared, ready-to-use media and for each batch of medium prepared by the laboratory.
- 5.9.3.4 Sterility checks on sample containers are performed on at least one container for each lot of purchased, pre-sterilized containers. For containers prepared and sterilized in the laboratory, a sterility check is performed on one container per sterilized batch with non-selective growth media.
- 5.9.3.5 A sterility blank is performed on each batch of dilution water prepared in the laboratory and on each batch of pre-prepared, ready-to-use dilution water with non-selective growth media.
- 5.9.3.6 At least one filter from each new lot of membrane filters is checked for sterility with non-selective growth media.
- 5.9.4 Positive culture controls: each pre-prepared, ready-to-use lot of medium and each batch of medium prepared in the laboratory is tested with at least one pure culture of a known positive reaction. This is done prior to first use of the medium.
- 5.9.5 Negative Controls: each pre-prepared, ready-to-use lot of selective medium and each batch of selective medium prepared in the laboratory is analyzed with one or more known negative culture controls, i.e. non-target organisms, as appropriate to the method. This is done prior to first use of the medium.

Results

- 5.9.6 Test Variability/Reproducibility: For test methods that specify colony counts such as membrane filter or plated media, duplicate counts are performed monthly on one positive sample, for each month that the test is performed. If the lab has two analysts, each analyst counts typical colonies on the same plate. Counts must be within 10% difference to be acceptable. If only one microbiology analyst is present, the same plate is counted twice by the analyst, with no more than 5% difference between the counts.
- 5.9.7 Test Performance:
- 5.9.7.1 All growth and recovery media are checked to assure that the target organism(s) respond in an acceptable and predictable manner.
- 5.9.7.2 To ensure that analysis results are accurate, target organism identity is verified as specified in the method, e.g. by use of the completed test, or by use of secondary verification tests such as a catalase test.
- 5.9.8 Quality of Standards, Reagents, and Media: the laboratory ensures that the quality of the reagents and media used is appropriate for the test concerned.
- 5.9.8.1 Culture media may be prepared from commercial dehydrated powders or may be purchased ready to use. Media may be prepared by the laboratory from basic ingredients when commercial media are not available or when it can be demonstrated that commercial media do not provide adequate results. Media prepared by the laboratory from basic ingredients is tested for performance prior to first use. Detailed testing criteria information is defined in either the laboratory's test methods, SOP's, Quality Manual, or similar documentation.
- 5.9.8.2 Reagents, commercial dehydrated powders and media are used within the shelf-life of the product and are documented according to 5.6.4.
- 5.9.8.3 Distilled water, deionized water or reverse-osmosis produced water from bactericidal and inhibitory substances are used in the preparation of media, solutions and buffers. The quality of the water is monitored for chlorine residual, specific conductance, and heterotrophic bacteria plate count monthly, when in use, when maintenance is performed on the water treatment system, or at startup after a period of disuse longer than one month. Analysis for metals and Bacterial Water Quality Test to determine presence of toxic agents or growth promoting substances is performed annually. Results of these analyses shall meet the specifications of the required method and records of analyses are maintained for five years. Exception: if documentation is supplied to show that the water source meets the criteria, as specified by the method, for Type 1 or type 2 reagent water.

Results

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- 5.9.8.4 Media, solutions, and reagents are prepared, used, and stored according to a documented procedure following manufacturer's instructions or the test method. Documentation for media prepared in the laboratory includes date of preparation, preparer's initials, type and amount of media prepared, manufacturer and lot number, final pH of the media, and expiration date. Documentation for media purchased pre-prepared, ready-to-use includes manufacturer, lot number, type and amount of media received, date of receipt, expiration date of the media, and pH of the media.
- 5.9.9 Selectivity: In order to ensure identity and traceability, reference cultures used for positive and negative controls are obtained from a recognized national collection, organization, or manufacturer recognized by the NELAP Accrediting Authority. Microorganisms may be single use preparations or cultures maintained by documented procedures that demonstrate the continued purity and viability of the organism.
- 5.9.9.1 Reference cultures may be revived if freeze dried or transferred from slants and subcultured once to provide reference stocks. The reference stocks are preserved by a technique which maintains the characteristics of the strains. Reference stocks are used to prepare working stocks for routine work. If reference stocks have been thawed, they must not be re-frozen and re-used.
- 5.9.9.2 Working stocks are not sequentially cultured more than five times and are not subcultured to replace reference stocks.
- 5.9.9.3 Annual or quarterly proficiency tests are performed to maintain quality control and to update Demonstration of Capability forms for all employees. Proficiency tests are either purchased from external PT programs or are spiked in-house using standards of known integrity.

Responsibility

Laboratory Manager

References

Personnel demonstration of capability notebook

SOP () Preparation and procedure for processing of internal and external QC and PT samples

Procedures

Quality Policy Manual

5.10 Reporting Results

Policy

Source Molecular Corporation ensures that the testing results are delivered properly. Source Molecular Corporation does not produce calibration reports.

Quality System Requirements

5.10.1 General: Results are reported accurately, clearly, unambiguously and objectively, and in accordance with any specific instructions in the test methods. Results reported in test report that includes all the information requested by the client and necessary for the interpretation of the results and methods used. For internal clients, or with written agreement with client, results may be reported in a simplified way. All information required by 5.10.2 to 5.10.4 shall be readily available in the lab that performed the testing.

5.10.1.1 The in-house laboratory is itself responsible for preparing the regulatory reports, or:

5.10.1.2 The laboratory provides information to another individual within the organization for preparation of regulatory reports. The facility management ensures that the appropriate report items are in the report to the regulatory authority if such information is required.

5.10.2 Test Reports: include the following information, unless the laboratory has a valid reason for not doing so, as indicated by 5.10.1.1 and 5.10.1.2.

5.10.2.1 Title.

5.10.2.2 Name and address of lab and location where testing was performed, if different from lab, and phone number with name of contact person for questions.

5.10.2.3 Unique identification of report, and on each page an identification to ensure that the page is recognized as a part of the report and a clear indication of the end of the report.

5.10.2.3.1 This requirement may be presented in several ways:

5.10.2.3.1.1 The total number of pages may be listed on the first page of the report as long as the subsequent pages are identified by the unique report identification and consecutive numbers.

5.10.2.3.1.2 Each page is identified with the unique report identification. The pages are identified as a number of total report pages.

5.10.2.3.2 Other methods of identifying the page in the report may be acceptable as long as it is clear to the reader that discrete pages are associated with a specific report, and that the report contains a specified number of pages.

5.10.2.4 Name and address of client and project name if applicable.

5.10.2.5 Identification of the method used.

5.10.2.6 Description, condition, and unambiguous identification of the sample(s), including client identification code.

5.10.2.7 Date of receipt of sample(s), where critical to validity and application of the results. Date and time of sample collection, Date(s) of performance of testing, and time of sample preparation and/or analysis if the required holding time for either activity is less than or equal to 72 hours.

Quality Policy Manual**5.10 Reporting Results**

- 5.10.2.8 Reference to the sampling plan and procedures.
- 5.10.2.9 Testing results with, where appropriate, the units of measurement, and any failures identified; identify whether data are calculated on a dry weight or wet weight basis; identify reporting units such as ug/L or mg/kg.
- 5.10.2.10 Name(s), functions, and signatures of personnel authorizing the test report, and date of issue.
- 5.10.2.11 A statement to the effect that the results relate only to the samples.
- 5.10.2.12 At the laboratory's discretion, a statement that the report shall not be reproduced except in full, without the written approval of the laboratory.
- 5.10.2.13 Certification that the test results meet all requirements of NELAC or provide reasons and/or justification if they do not.
- 5.10.3 Supplemental information for test reports:
- 5.10.3.1 Where necessary for the interpretation of results, the following shall be included in test reports:
- 5.10.3.1.1 Deviations from (e.g. failed quality control), additions to, or exclusions from the test method, and information on specific test conditions, such as environmental conditions and any non-standard conditions that may have affected the quality of results, including the use and definitions of data qualifiers.
- 5.10.3.1.2 Where quality system requirements are not met, a statement of compliance/ non-compliance with the requirements and/or specifications, including identification of test results derived from any sample that did not meet NELAC sample acceptance requirements such as improper container, holding time, or temperature.
- 5.10.3.1.3 Where applicable, a statement of the estimated uncertainty of measurement, particularly if the client's instruction so requires.
- 5.10.3.1.4 Where appropriate and needed, opinions and interpretations.
- 5.10.3.1.5 Additional information required by specific methods, clients or groups of clients.
- 5.10.3.1.6 Qualifications of numerical results with values outside the working range.
- 5.10.3.2 Test reports containing the results of sampling, when necessary, include for the interpretation of the test results:
- 5.10.3.2.1 Date of sampling
- 5.10.3.2.2 Unambiguous identification of the substance, material or product sampled, including name of manufacturer, model or type of designation and serial numbers as appropriate.
- 5.10.3.2.3 Location of sampling, including any diagrams, sketches and photographs.
- 5.10.3.2.4 Reference to sampling plan and procedure used.
- 5.10.3.2.5 Details of environmental conditions during sampling that may affect the interpretations of the test results.
- 5.10.3.2.6 Standard or specification for the sampling method or procedure, and deviations, additions to or exclusions from the specification concerned.

- 5.10.4 Opinions and Interpretations: When opinions and interpretations are included, the basis for such opinions and interpretations are documented and marked as such on the test reports.
- 5.10.5 Testing results obtained from subcontractors : Subcontracted test results are clearly identified on the test reports. The subcontractor shall report the results in writing or electronically. The laboratory shall make a copy of the subcontractor’s report available to the client when requested by the client.
- 5.10.6 Electronic Transmission of Results: Results transmitted by telephone, telex, fax, or other electronic or electromagnetic means shall meet the requirements of this Standard and ensure that all reasonable steps are taken to preserve confidentiality.
- 5.10.7 Format of Reports and Certificates: Format is designed to accommodate each type of test carried out and to minimize the possibility of misunderstanding or misuse.
- 5.10.8 Amendments to Reports: Material amendments to the test reports after issue are made through further documents or data transfer which includes statement: "Supplement to Test Report, serial number...[or as otherwise identified]" or equivalent form of wording. Such amendments shall meet all the requirements of this Standard. When necessary to issue a complete new report, this will be uniquely identified and contain reference to the original that it replaces.
- 5.10.9 Data Reduction: The calculations, data reduction and statistical interpretations specified by each test method are followed.

Responsibility

Laboratory Directors

References

Procedures

Reporting (SOP Q-5)

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5.11 Data Integrity

Policy

Source Molecular Corporation ensures data integrity is maintained.

Quality System Requirements

- 1.11.1 All laboratory staff involved in data storage and retrieval and report generation are trained in maintaining data integrity.
 - 1.11.2 Signed data integrity documentation is kept on file for all laboratory employees undergoing said training.
 - 1.11.3 Data integrity is monitored periodically and in depth.
 - 1.11.4 Documentation of the data integrity procedure is kept on file.
 - 1.11.5 Data integrity issues in the laboratory may be reported confidentially to management, who maintain confidentiality and a receptive environment.
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Responsibility

Quality Manager

References

Data Integrity SOP (Q 9)

Procedures

Term	Definition
Accuracy	A measure of the difference (bias) between the Average of the readings from a measurement System and a corresponding benchmark or Master.
Benchmark Data	The results of an investigation to determine how Competitors and/or best-in-class Companies achieve their level of performance.
Capability	Capability is the total range of a stable process's inherent variation. It is determined using data from control charts. Reference "Fundamental Statistical Process Control".
Certified Registrars	Certified Registrars are qualified organizations certified by a national body (e.g., the Registrar Accreditation Board in the U.S.) to perform audits of the Quality System Requirements and to register the audited facility as meeting these requirements for a given commodity.
Conformity	The fulfillment of specified requirements.
Corrective Action Plan	A Corrective Action Plan is a plan for correcting a process or part quality issue.
Customer	The recipient of a product provided by the supplier.
Environment	Environment is all of the conditions surrounding and affecting manufacture and quality of a part or product.
Functional Verification	Functional Verification is testing to ensure the Part conforms to all customer and supplier engineering performance and material requirements.
Inspection	An activity such as measuring, examining, testing of 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.
Non-conformance	Non-conformance is product or material, which does not conform to the customer requirements or specifications.
Objective Evidence	Information, which can be proved true, based on facts obtained through observation, measurement, test or other means.
Ongoing Process	Ongoing process capability is a long term Capability measure of statistical process control, or process performance. Reference Fundamental SPC Reference Manual.
Organization	A company, corporation, firm, enterprise, or institution, or part thereof, whether incorporated or not, public or private, that has its own functions an administration.

Quality Policy Manual

Glossary

Term	Definition
Parts Per Million (PPM)	PPM is a measure of process performance in terms of actual or projected non-conforming material. In general use, PPM defective is expressed as the proportion non-conforming (defective parts/total parts) times 1,000,000.
Preliminary Process Performance Studies	Preliminary Process Performance Studies are short-term studies conducted to obtain early information on the performance of new or revised processes relative to internal or customer requirements.
Procedure	A specified way to perform an activity. A documented procedure usually contains the purpose and scope of an activity; what shall be done and by whom; when, where and how it shall be done; what materials, equipment and documents shall be used; how it shall be controlled and recorded.
Process	A set of interrelated resources and activities, which transform input into, output.
Product	The result of activities or processes. Product includes service, hardware, processed materials, software, or a combination thereof. Product can be tangible or intangible or a combination of both Product can be intended or unintended.
Qualified	The status given to an entity when it has been demonstrated to be capable of fulfilling specified requirements.
Quality	The totality of characteristics of an entity that bear on its ability to satisfy stated and implied needs.
Quality Manual	Quality Manual (also known as the Quality System Plan) is a document that describes the elements of the quality system used to assure customer requirements; needs and expectations are met. Quality manuals include responsibilities and authorities for each element of the quality system.
Quality Plan	A document identifying the specific quality practices, resources and sequence of activities relevant to a particular product, project, or contract.
Quality Planning	Quality Planning is a structured process for defining the methods (i.e., measurements, tests) that will be used in the production of a specific product or family of products (i.e., parts, materials.)
Quality Policy	The overall intentions and direction of an organization with regard to quality, as formally expressed by top management. The quality policy is one element of the corporate policy.

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Glossary

Term	Definition
Quality Record	A document which provides objective evidence of the extent of the fulfillment of the requirements for quality or the effectiveness of the operation of a quality system element.
Registered Suppliers/ Subcontractors	Registered Suppliers/Subcontractors are suppliers/subcontractors who have received third party ISO 9000 certification of the commodity supplied.
Registrar	A Registrar is a company that conducts quality system assessments to ISO 9000 Requirements.
Reliability	The probability that an item will continue to function at customer expectation levels at a measurement point, under specified environmental and duty cycle conditions.
Repair	The action taken on a nonconforming product so that it will fulfill the intended usage requirements, although it may not conform to originally specified requirements.
Rework	The action that will be taken on a nonconforming product so that it will fulfill the specified requirements.
Service	The results generated by activities at the interface between the supplier and the customer and by supplier internal activities, to meet customer needs.
Setup Verification	Formal review of process start-up (including equipment, tooling, material and conditions) to ensure that acceptable parts will be provided,
Special Characteristics	Product and process characteristics designated by the customer, including governmental regulatory and safety, and/or selected by the supplier through knowledge of the product and the process.
Special Processes	Production, installation and servicing processes requiring pre-qualification of process capability. This requirement is usually due to the inability to verify the process by subsequent inspection and testing of the product or where processing deficiencies may become apparent only after the product is in use.
Stability	The stability of a measurement system variation over time.
Statistical Process Control	The use of statistical techniques such as control charts to analyze a process or its output so as to take appropriate actions, which achieve and maintain a state of statistical control and improve the capability of the process.
Subcontractors	Subcontractors are defined as providers of materials, parts or services to a supplier.

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Term	Definition
Supplier	The organization that provides a product to the customer.
Validation	Confirmation by examination and provision of objective evidence that the particular requirements for a specific intended use are fulfilled.
Verification	Confirmation by examination and provision of objective evidence that the specified requirements have been met.
Visual Controls	Visual controls are techniques for conveying information by visual means to observers so that everyone can understand whether current conditions are normal. Examples are floor markings, action boards, standardized work Charts and color-coding.