

Gulf Coast Testing, LLC



Laboratory and Certification Program Quality Manual

Certification Office

5261 Highland Road Box 347
Baton Rouge, LA 70808



Laboratory & Test Site

14378 Park Avenue
Prairieville, LA 70769


Eric Holland, Laboratory Manager
225-397-0633
eric.holland@gctlac.com

Written per
ISO/IEC 17065:2012 (E)
ISO/IEC 17025:2017
ISO/IEC 17020:2012
TNI Standard:2016



December 15, 2020



 GULF COAST TESTING, LLC	GULF COAST TESTING, LLC	DOCUMENT CODE	GCT-DOC001
	QUALITY MANUAL	REVISION	03
		EFFECTIVE DATE	12/15/2020
	PREFACE		

Introduction

The Gulf Coast Testing, LLC (GCT) Laboratory located at 14378 Park Avenue, Prairieville, Louisiana was established in 2002 at the GCT test site as an extension of its certification services. The laboratory originally started in a small trailer and was relocated to larger building on the test site in 2015. The Laboratory has since gained NELAP certification in 2015 and is key to GCT's certification business.

The purpose of the GCT Laboratory is to provide GCT with low cost, high quality testing service in support of its wastewater certification program and other business activities. Quality testing allows GCT to obtain dependable results for certification activities, and the low cost enables GCT to offer its certification services at a competitive price.

The GCT Laboratory is self-funded by its certification program and non-certification wastewater testing. The laboratory is headed by a Technical Director who is also the Quality Assurance Officer. The use of state-of-the-art, analytical equipment, methods and facilities is critical to the success of the laboratory.

Mission – Quality Policy Statement

THE Gulf Coast Testing, LLC Laboratory is committed to providing wastewater laboratory services through reliable and accurate test results that lead to customer satisfaction by implementing a quality management system as per ISO/IEC 17065, ISO/IEC 17025, and the TNI Standard.

The GCT Laboratory and staff are committed to continually improve the effectiveness of its quality Management System through review and training for all employees and to make the laboratory known for its quality testing and services.

Core Values

At the GCT Laboratory we hold the following principles and values to be the most important, and we consider these values in making decisions:

- honesty
- safety of our employees and community
- good science
- fairness
- quality

Ethics Policy

Ethics is a set of moral principles, a code for right and wrong, or behavior which conforms to accepted professional practices. ***All employees at all times shall conduct themselves in an honest and ethical manner.*** Examples of unethical behavior include, but are not limited to the following:

- Improper manipulation of data or software
- Improper handling of data errors, non-compliant data, or QC outliers
- Lack of reporting unethical behavior by others
- Artificially fabricating results
- Improper clock setting to meet holding times
- Intentional deletion of non-compliant data

An employee must report any suspected unethical behavior or fraudulent activities to a supervisor. An employee has the right to remain anonymous.

Confidentiality

Client information is confidential and will not be discussed with anyone, even those affiliated with the client not designated as a contact, without permission from the client. Confidential information includes test results, origin of samples, business relationship with the client, any procedures and testing that they conduct or investigate, and information about their certification activities.

Analytical Services

The laboratory maintains state-of-the-art analytical equipment. Major pieces of equipment include:

Seal Analytical Discrete Analyzer
Seal Digestion Block
IDEXX Colilert-18 System
Hach LBOD101 DO Probe
Thermo Scientific BOD Incubator
Sartorius Balance

Testing Services information - details available on the laboratory website

Wastewater testing includes tests for water quality, including sediment, nutrients, alkalinity and fecal coliform, total coliform and E Coli. The GCT laboratory is NELAP certified for pH, BOD₅, CBOD₅, and TSS.

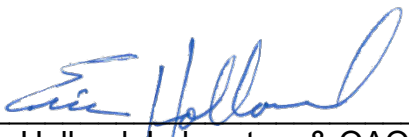
Quality Control and Quality Assurance

Quality Control (QC) refers to steps taken to ensure and monitor precision and accuracy of test results. Quality Control practices include the analysis of quality control samples with each set of samples. These include calibration standards, certified reference materials, spiked samples, duplicate sample analysis, and blanks.

Quality Assurance (QA) refers to a separate and independent monitoring of laboratory studies and Quality Control activities. Quality Assurance activities include the participation in proficiency programs, review of data packages and evaluation of nonconformances.

This Quality Manual defines and clarifies policies, systems, and procedures adopted to implement and to continuously improve the Quality Management System (QMS) of Gulf Coast Testing, LLC. This Quality Manual, together with associated documents referenced in the scope, aims to describe the basic elements of the QMS of Gulf Coast Testing, LLC and serve as reference in its implementation and continuous improvement; inform all our customers, vendors, and clients so as to enable them to participate in the implementation of the QMS of Gulf Coast Testing, LLC; and fulfill the requirements of ISO/IEC 17065 (2012), ISO/IEC 17025 (2017), TNI Standard (2016) and the Standards.

The previous Quality Assurance Manuals are kept for historical and reference purposes on GCT's cloud server pursuant to Gulf Coast Testing, LLC's Document Control and Retention policy. Inquiries regarding this Quality Manual can be directed to the Laboratory and QAQC Manager, Eric Holland, at eric.holland@gctla.com.


Eric Holland, Laboratory & QAQC Manager

12/15/2020
Date


William B. Daniel IV, Program Manager

12/15/2020
Date

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1.0 SCOPE

Gulf Coast Testing, LLC (GCT) is committed to its policy of providing high quality services with respect to residential wastewater treatment unit and component certification. This includes certifying new products, certifying previously certified products including those by other accredited organizations, changes in scope for units previously certified by GCT, continuing compliance, and environmental testing.

This document is for use by laboratories performing laboratory activities, clients, regulatory authorities, and accreditation bodies to ensure GCT's laboratory has appropriate management and technical quality systems to perform environmental testing. This document specifies technical, managerial, and documentation requirements needed for assessment by organizations or accreditation bodies to grant approval, and to confirm or recognize the competence of laboratories.

To ensure that GCT's policy of providing high quality service is realized, GCT has a "Quality Procedures" document and "Quality Forms" applicable to the activities of GCT as referenced by this document. These procedures and the related forms state the objectives of GCT in its commitment to providing high quality service and are readily available to GCT's employees.

2.0 NORMATIVE REFERENCES

- a) NSF/ANSI Standard 40 (2019) - Residential Wastewater Treatment Systems (hereafter referred to as Standard 40)
- b) NSF/ANSI Standard 245 (2019) - Wastewater Treatment Systems – Nitrogen Reduction (hereafter referred to as Standard 245)
- c) NSF/ANSI Standard 46 (2018) - Evaluation of Components and Devices Used in Wastewater Treatment Systems (hereafter referred to as Standard 46)
- d) NSF/ANSI Standard 350 (2019) - Onsite Residential and Commercial Water Reuse Treatment Systems (hereafter referred to as Standard 350)
- e) NSF/ANSI Standard 350-1 (2017) - Onsite Residential and Commercial Graywater Treatment Systems for Subsurface Discharge (hereafter referred to as Standard 350-1)
- f) ISO/IEC 17000 (2004) - Conformity assessment -- Vocabulary and general principles
- g) ISO/IEC 17020 (2012) - General criteria for the operation of various types of bodies performing inspections
- h) ISO/IEC 17025 (2017) - General Requirements for the competence of testing and calibration laboratories
- i) ISO/IEC 17065 (2012) - General Requirements for the Bodies Operating Product Certification Systems
- j) Standard Methods for the Examination of Water and Wastewater (23rd edition)
- k) ISO/IEC 17030 (2003) - General Requirements for Third-Party Marks of Conformity
- l) ISO/IEC Guide 99 - *International vocabulary of metrology — Basic and general concepts and associated terms (VIM)*
- m) TNI Standard (2016) – Management and Technical Requirements for Laboratories Performing Environmental Analysis

3.0 TERMS AND DEFINITIONS

The relevant terms and definitions are quoted below for the purposes of this document.

3.1. Client

The Client is the entity conducting the certification of conformity to the requirements of any referenced standard and GCT's policies and procedures. The Client may be the manufacturer distributor, supplier, or other party providing the product who is responsible for assuring conformity with all requirements of any of the referenced standards or specifications, and who desires to participate in the certification program and have its product(s) certified. The Client shall have a qualified and trained staff capable of handling the administrative functions required to provide the service, the facilities and instrumentation adequate and appropriate for handling the service.

3.2. Consultancy

Consultancy refers to the personnel employed or contracted by GCT responsible for ensuring that products meet and, if applicable, continue to meet, the requirements on which certification is based according to ISO/IEC 17065. In this manual, consultancy refers to the activities of GCT and organizations related or linked to GCT.

- a) Designing, manufacturing, installing, maintaining, or distributing of a certified product or a product to be certified
- b) Designing, implementing, operating, or maintaining of a certified process or process to be certified
- c) Designing, implementing, providing, or maintaining of a certified service or service to be certified

3.3. Evaluation

Evaluation includes all GCT's planning and preparation activities needed for product certification, including conformity to the Standards. Evaluation refers to the systematic examination of the extent to which the design fulfills specified requirements as specified in ISO/IEC 17000:2004, Clauses A.2 and A.3.

3.4. Product

The product is a result of a process. GCT reviews the processes of residential wastewater systems and components to determine if the product of the system or component conforms to the Standards.

3.5. Process

A process is a set of interrelated activities which transforms inputs into outputs. GCT reviews the process of residential wastewater systems and components.

3.6. Service

Service is the result of the activities performed between the supplier and client. GCT reviews the activities of the supplier performed for the client to ensure compliance with the Standard.

3.7. Certification Requirements

A certification requirement is a specified requirement that is fulfilled by the Client as a condition of establishing or maintaining certification. GCT's certification requirements are listed in GCT's Quality Procedures.

3.8. Product Requirement

A product requirement is a specified requirement that is fulfilled by the Client as a condition of establishing or maintaining certification. GCT's certification requirements are the criteria established in the Standards.

3.9. Certification Scheme

A certification scheme is the organizational structure, responsibilities, procedures, processes, and resources for implementing product certification. GCT has Quality Procedures and Quality Forms as part of its certification scheme.

3.10. Scopes of Certification

The scope of certification is the identification of the products for which certification is granted, the applicable certification scheme, and the Standards used to ensure the products comply. GCT's scopes of certification are residential wastewater treatment unit and component certification. This includes certifying new products, continuing compliance, certifying previously certified products including those by other accredited organizations and changes in scope for units previously certified by GCT.

3.11. Scheme Owner

The scheme owner is the organization responsible for maintaining the certification scheme. GCT is the scheme owner.

3.12. Certification Body

The Certification Body is the party that is responsible for ensuring that products meet and, if applicable, continue to meet, the requirements on which certification is based according to ISO/IEC 17065. GCT is the certification body.

3.13. Impartiality

Impartiality means the certification body should be free from biases and conflicts of interest so that it can make objective decisions regarding certification. GCT's certification scheme, Quality Procedures, and Quality Forms insures its impartiality.

3.14. Standard

A Standard is a format that has been approved by a recognized standards organization. GCT uses standard developed by NSF. NSF is accredited by the American National Standards Institute (ANSI) to develop and publish American National Standards and has published numerous standards for residential wastewater and wastewater components. The standards used by GCT are listed in the Reference Section of Chapter 2 of this Quality Manual. Collectively, they are referred to as the Standards.

3.15. Supplier

A supplier can be a client, manufacturer, or an agent of the manufacturer that offers certified products to the public.

3.16. Test

A test is a technical operation that consists of the determination of one or more characteristics or performance of a given product, material, equipment, organism, physical phenomenon, process, or service according to a specified procedure.

3.17. Conformity

Conformity is the fulfillment by a product, process, or service of specified requirements. The purpose of the GCT scheme is ensuring conformity to the Standards.

3.18. Nonconformity

Non-conformity is the absence of one or more specified requirements of the Standards or of GCT's Quality Procedures.

3.19. Quality Manual

A document stating the quality policy, quality system and quality practices of an organization.

3.20. Laboratory Technical Manager

GCT's Laboratory Technical Manager is a member of the staff of an environmental laboratory who exercises actual day-to-day supervision of laboratory operations for the appropriate fields of accreditation and reporting of results. The GCT Laboratory Technical Manager is experienced in the fields of accreditation for which the laboratory is seeking accreditation.

3.21. QA/QC Officer (Certification)

The QA/QC officer assesses GCT's compliance with its policies and procedures and reports to the GCT Program Manager. GCT uses the title Deputy Manager and QA/QC officer interchangeably.

3.22. QA/QC Officer (Laboratory)

GCT's QA/QC officer creates systems to monitor data quality and performance. The QA/QC Officer also confirms that procedures adhere to safety and compliance rules and regulations. The QA/QC Officer's job is to conduct testing in a timely manner, personally reviewing any abnormal results to find the root of the irregularity. The QA/QC Officer also hires and manages staff, ensuring that all employees receive proper training. The QA/QC Officer may also dialogue with vendors, also verifying whether they follow the lab's standards. The GCT QA/QC Officer is also GCT's Laboratory Manager and Technical Manager.

3.23. Laboratory

The laboratory is the body that calibrates, samples, and/or evaluates the product or intermediate products in the process. GCT's laboratory is located at its test site and is the laboratory for certification unless otherwise noted in GCT's SOP's. GCT's laboratory follows the requirements of ISO/IEC 17025.

3.24. Off-Site Testing

On-site testing, in the context of this document, refers to the test site when the test site is other than at the GCT lab or office.

3.25. Qualified Personnel

Personnel that have demonstrated the capability of fulfilling specified requirements.

3.26. Model

A model is a type or version of a product submitted to GCT for evaluation.

3.27. Accreditation Body

The territorial, state, or federal agency having responsibility and accountability for environmental laboratory accreditation and which grants accreditation. GCT is an accreditation body for on-site wastewater accreditation.

3.28. Acceptance Criteria

Specified limits placed on the characteristics of an item, process, or service defined in requirement documents.

3.29. Accuracy

The degree of agreement between an observed value and an accepted reference value. Accuracy includes the combination of random error (precision) and systemic error (bias) components that are due to sampling and analytical operations, a data quality indicator.

3.30. Analytical Uncertainty

A subset of measurement uncertainty that includes all laboratory activities performed as part of the analysis.

3.31. Batch

Environmental samples that are prepared and/or analyzed together with the same process and personnel, using the same lot(s) of reagents. A preparation batch is composed of ten (10) environmental samples of the same quality systems matrix, meeting the above-mentioned criteria and with a maximum time between the start of processing of the first and last sample in the batch to be twenty-four (24) hours.

3.32. Analytical batch

An analytical batch is composed of prepared environmental samples (extracts, digestates or concentrates) which are analyzed together as a group. An analytical batch can include prepared samples originating from various quality system matrices and can exceed twenty (20) samples.

3.33. Bias

The systematic or persistent distortion of a measurement process, which causes errors in one direction (i.e., the expected sample measurement is different from the sample's true value).

3.34. Blank

A sample that has not been exposed to the analyzed sample stream to monitor contamination during sampling, transport, storage, or analysis. The blank is subjected to the usual analytical and measurement process to establish a zero baseline or background value and is sometimes used to adjust or correct routine analytical results. A method blank is a sample of a matrix similar to the batch of associated samples (when available) that is free from the analytes of interest and is processed simultaneously with and under the same conditions as samples through all steps of the analytical procedures, and in which no target analytes or interferences are present at concentrations that impact the analytical results for sample analyses.

3.35. Calibration

A set of operations that establish, under specified conditions, the relationship between values of quantities indicated by a measuring instrument or measuring system, or values represented by a material measure or a reference material, and the corresponding values realized by standards.

- a) In calibration of support equipment, the values realized by the standards are established using reference standards that are traceable to the International System of Units (SI).
- b) In calibration according to methods, the values realized by standards are typically established using Reference Materials that are either purchased by GCT's laboratory with a certificate of analysis, purity, or prepared by the laboratory using support equipment that has been calibrated or verified to meet specifications.

3.36. Calibration Curve

The mathematical relationship between the known values, such as concentrations, of a series of calibration standards and their instrument response.

3.37. Calibration Standard

A substance or reference material used for calibration.

3.38. Chain of Custody

Record that documents the possession of the samples from the time of collection to receipt in GCT's laboratory. This record generally includes: the number and types of containers; the mode of collection; the collector; time of collection; preservation; and requested analyses.

3.39. Demonstration of Capability

A procedure to establish the ability of the analyst to generate analytical results of acceptable accuracy and precision.

3.40. Field of Accreditation

Those matrix, technology/method, and analyte combinations for which the accreditation body offers accreditation.

3.41. Finding

An assessment conclusion referenced to a laboratory accreditation standard and supported by objective evidence that identifies a deviation from a laboratory accreditation standard requirement.

3.42. Laboratory Control Sample

A sample matrix, free from the analytes of interest, spiked with verified known amounts of analytes or a material containing known and verified amounts of analytes and taken through all sample preparation and analytical steps of the procedure unless otherwise noted in a reference method. It is generally used to establish intra-laboratory or analyst specific precision and bias or to assess the performance of all or a portion of the measurement system.

3.43. Legal Chain of Custody Protocols

Procedures employed to record the possession of samples from the time of sampling through the retention time specified by the client or program. These procedures are performed at the special request of the client and include the use of a Chain of Custody Form that documents the collection, transport, and receipt of compliance samples by GCT's laboratory. In addition, these protocols document all handling of the samples within the laboratory.

3.44. Limit(s) of Detections (LOD)

A laboratory's estimate of the minimum amount of an analyte in a given matrix that an analytical process can reliably detect in their facility.

3.45. Limit(s) of Quantification (LOQ)

The minimum levels, concentrations, or quantities of a target variable (e.g., target analyte) that can be reported with a specified degree of confidence.

3.46. Matrix

The substrate of a test sample.

3.47. Matrix Duplicate

A replicate matrix prepared in the laboratory and analyzed to obtain a measure of precision.

3.48. Matrix Spike

A sample prepared, taken through all sample preparation and analytical steps of the procedure unless otherwise noted in a referenced method, by adding a known amount of target analyte to a specified amount of sample for which an independent test result of target analyte concentration is available. Matrix spikes are used, for example, to determine the effect of the matrix on a method's recovery efficiency.

3.49. Matrix Spike Duplicate

A replicate matrix spike prepared in the laboratory and analyzed to obtain a measure of the precision of the recovery for each analyte.

3.50. Measurement System

A method, as implemented at a laboratory, and which includes the equipment used to perform the test and the operator(s).

3.51. Method

A body of procedures and techniques for performing an activity (e.g., sampling, chemical analysis, quantification), systematically presented in the order in which they are to be executed.

3.52. Mobile Laboratory

A portable enclosed structure with necessary and appropriate accommodation and environmental conditions for a laboratory, within which testing is performed by analysts.

3.53. Precision

The degree to which a set of observations or measurements of the same property, obtained under similar conditions, conform to themselves, a data quality indicator. Precision is usually expressed as standard deviation, variance, or range, in either absolute or relative terms.

3.54. Preservation

Any conditions under which a sample must be kept to maintain chemical and/or biological integrity prior to analysis.

3.55. Procedure

A specified way to conduct an activity or process. Procedures can be documented or not.

3.56. Proficiency Testing

A means of evaluating a laboratory's performance under controlled conditions relative to a given set of criteria through analysis of unknown samples provided by an external source.

3.57. Proficiency Testing Program

The aggregate of providing rigorously controlled and standardized environmental samples to a laboratory for analysis, reporting of results, statistical evaluation of the results and the collective demographics and results summary of all participating laboratories.

3.58. Proficiency Testing Sample

A sample, the composition of which is unknown to GCT's laboratory and is provided to evaluate whether the laboratory can produce analytical results within the specified acceptance criteria.

3.59. Protocol

A detailed written procedure for field and/or laboratory operation (e.g., sampling, analysis) which must be strictly followed. GCT uses SOP (Standard Operating Procedure) interchangeably with Protocol.

3.60. Quality Assurance

An integrated system of management activities involving planning, implementation, assessment, reporting, and quality improvement to ensure that a process, item, or service is of the type and quality needed and expected by the client.

3.61. Quality Control

The overall system of technical activities that measures the attributes and performance of a process, item, or service against defined standards to verify that they meet the stated requirements established by the client; operational techniques and activities that are used to fulfill requirements for quality; also the system of activities and checks used to ensure that measurement systems are maintained within prescribed limits, providing protection against "out of control" conditions and ensuring that the results are of acceptable quality.

3.62. Quality Control Sample

A sample used to assess the performance of all or a portion of the measurement system. One of any number of samples, such as Certified Reference Materials, a quality system matrix fortified by spiking, or actual samples fortified by spiking, intended to demonstrate that a measurement system or activity is in control.

3.63. Raw Data

The documentation generated during sampling and analysis. This documentation includes, but is not limited to, field notes, electronic data, magnetic tapes, un-tabulated sample results, QC sample results, print outs of chromatograms, instrument outputs, and handwritten records.

3.64. Reference Material

Material or substance one or more of whose property values are sufficiently homogeneous and well established to be used for the calibration of an apparatus, the assessment of a measurement method, or for assigning values to materials.

3.65. Reference Standard

Standard used for the calibration of working measurement standards in a given organization or at a given location.

3.66. Reference Method

A reference method is a method issued by an organization generally recognized as competent to do so. When a laboratory is required to analyze a parameter by a specified method due to a regulatory requirement, the parameter/method combination is recognized as a reference method.

3.67. Sampling

Activity related to obtaining a representative sample of the object of conformity assessment, according to a procedure.

3.68. Complaint

An expression of dissatisfaction by any person or organization to a laboratory, relating to the activities or results of that laboratory, where a response is expected by the complainant.

3.69. Interlaboratory Comparison

The organization, performance and evaluation of measurements or tests on the same or similar items by two or more laboratories in accordance with predetermined conditions.

3.70. Intralaboratory Comparison

The organization, performance and evaluation of measurements or tests on the same or similar items within the same laboratory in accordance with predetermined conditions.

3.71. Decision Rule

The rule that describes how measurement uncertainty is accounted for when stating conformity with a specified requirement.

3.72. Validation

Verification of where the specified requirements are adequate for an intended use.

3.73. Standard Operating Procedure (SOP)

A written document that details the method for an operation, analysis, or action, with thoroughly prescribed techniques and steps. SOPs are officially approved as the methods for performing certain routine or repetitive tasks.

3.74. Traceability

The ability to trace the history, application, or location of an entity by means of recorded identifications. In a calibration sense, traceability relates measuring equipment to national or international standards, primary standards, basic physical constants or properties, or reference materials. In a data collection sense, it relates calculations and data generated throughout the project back to the requirements for the quality of the project.

3.75. Verification

Confirmation by examination and objective evidence that specified requirements have been met. In connection with the management of measuring equipment, verification provides a means for checking that the deviations between values indicated by a measuring instrument and corresponding known values of a measured quantity are consistently smaller than the maximum allowable error defined in a standard, regulation, or specification peculiar to the management of the measuring equipment.

4.0 GENERAL REQUIREMENTS

4.1 Legal and Contractual Matters

4.1.1 Legal Responsibility

Gulf Coast Testing, LLC is a [legal entity](#) registered as a Limited Liability Company to do business in the State of Louisiana as of August 9, 2002 with [Articles of Organization](#) filed with the Louisiana Secretary of State's Office. The Program Manager/Owner has responsibility for all activities of GCT. GCT's laboratory is a part of GCT. The GCT Laboratory Manager has responsibility for the activities of the laboratory.

4.1.2 Certification Agreement

4.1.2.1 Contract

- a) GCT has a Quality Form called [Contract for Standard Performance Evaluation](#) the client is required to execute as part of the certification process.
- b) Any differences between the request and the contract shall be resolved before laboratory activities commence. Each contract shall be acceptable both to GCT and the client. Deviations requested by the client shall not impact the validity of the results the integrity of the laboratory.
- c) The client shall be informed of any deviation from the contract.
- d) If a contract is amended after work has commenced, the contract review shall be repeated, and any amendments shall be communicated to all affected personnel.

4.1.2.2 Continuing Compliance

The contract for Standard Performance Evaluation and GCT's Quality Procedures ensure the client complies with the following:

- a. Fulfills the certification requirements
- b. Continues to fulfil the product requirements for ongoing certification
- c. Makes the necessary arrangements for the conduct of the evaluation including the conduct of the evaluation, examining documents and records, access to relevant equipment, investigation of complaints, and participation of observers
- d. Makes claims regarding certification consistent with the scope of certification

- e. Does not use its product certification in such a manner as to bring the certification body into disrepute and makes no misleading or unauthorized claims
- f. Discontinues use of all advertising material for its certified product upon reducing scope or suspension of the certification
- g. Follows GCT's procedures for distributing certification documents
- h. Follows GCT's procedures for distributing advertising brochures or other documents
- i. Follows GCT's procedures for the Use of the Mark and on other information related to conformity
- j. Keeps a record of all complaints regarding its certified products and makes those records available to the certification body and takes and documents the action taken to resolve the complaint
- k. Informs GCT of any changes that may affect its ability to conform with the certification requirements

4.1.3 Use of License, Certification, and Marks of Conformity

4.1.3.1 Use of License

GCT exercises control over the use and ownership over any licenses, certificates, marks of conformity, and any other mechanisms for product certification pursuant to [GCT's Quality Procedure QP15 - Marking the Product Procedure](#) and ISO/IEC Guide 23.

4.1.3.2 Misuse of Mark

Incorrect references to GCT's certification scheme or misleading use of GCT's Mark or any other document or mechanism indicating a product is certified shall be dealt with pursuant to GCT Quality Procedure 15 – Marking the Product Procedure.

4.2 Management of Impartiality

4.2.1 Impartiality

GCT is committed to impartiality. GCT's commitment to impartiality is reflected in its certification activities as evidenced through this Quality Manual, Quality Forms, SOP's, and Quality Procedures.

4.2.2 Responsibility

Overall structural impartiality is insured through GCT Quality Procedures and Quality Forms regarding final approval of data, test reports and evaluation reports. Participants in GCT certification testing and design evaluation activities must sign a contract to commit to being free from any commercial, financial, and other internal and external pressures that may adversely affect the quality of their work. GCT employee salaries and promotion are not dependent upon the commercial or technical success of any specific commercial activity.

4.2.3 Risks to Impartiality

GCT identifies risks to impartiality on an ongoing basis. GCT uses its Quality Procedures and Quality Forms to control risk and insure impartiality.

4.2.4 Minimizing Risk to Impartiality

GCT manages all risks to impartiality through its Quality Procedures, SOP's and Quality Forms.

4.2.5 Impartiality of Management

GCT's management is committed to impartiality. No single person within GCT has the authority to approve data, evaluations, or test reports. Multiple signatures are required for data, test, and evaluation reports.

4.2.6 GCT Consultants and Impartiality

GCT requires its employees and contractor to sign documents prohibiting the employee or consultant from:

- a) Designing, manufacturing, installing, distributing, or maintaining a certified product.
- b) Offering consultancy to any GCT client.
- c) Offering or providing management system consultancy or internal auditing to GCT's clients where the certification scheme requires the evaluation of client's management system.

4.2.7 Other Entities

GCT has no other legal entities or relationships with other legal entities that would compromise the impartiality of its certification activities.

4.2.8 Separate Legal Entities

GCT has no separate legal entities or relationships with other separate legal entities that would compromise the impartiality of its certification activities.

4.2.9 Consultancy

GCT does not market its activities with an organization that provides consultancy.

4.2.10 Prohibition of Consultancy

GCT does not allow employees or contract personnel to make decisions for a product for which they have ever provided consultancy for two years after the end of the consultancy as evidenced by GCT's Confidentiality and Disclosure Agreement.

4.2.11 Response to Risks of Impartiality

GCT shall respond to all risks to impartiality pursuant to its Quality Procedures and Quality Forms.

4.1.12 Actions of Employees and Consultants

GCT, through its Quality Procedures and Quality Forms, ensures its employees and consultants act impartial and free from any commercial, financial and/or other pressures which might influence the results of the certification process.

4.3 Liability and Financing

4.3.1 Ownership

GCT is a privately-owned facility that carries liability insurance.

4.3.2 Financial Resources

The individual applicants' fees fund GCT. GCT has been in existence since the year 2002 and supports its certification activities with funds from certification applicants. These funds will be adequate for covering all required activities to meet the procedures defined in the GCT Quality Procedures manual. GCT accounts related to inspection are independently reviewed each year.

4.4 Non-Discriminatory Conditions

4.4.1 Policy

GCT does not discriminate against applicants in any way other than what is outlined in ISO/IEC 17065 and ISO/IEC 17025 to ensure high quality results in its certification scheme.

4.4.2 Access to Certification

GCT makes its services accessible to all applicants whose activities fall within its scope of operation.

4.4.3 Non-Conditional Access

Access is not conditional upon the size of the Supplier or membership in any association or group, nor is certification conditional upon the number of certificates already issued. There are no undue financial conditions; specifically, fees are invoiced monthly as services are performed. The procedures by which GCT administers engineering evaluations and annual continuing compliance audits are detailed in GCT's procedure for Evaluation Process and New and Continuing Compliance Reports.

4.4.4 Scope of Certification

GCT confines its certification activities to residential wastewater treatment and components of residential wastewater treatment. The GCT laboratory is accredited the activities shown in Appendix C.

4.5 Confidentiality

4.5.1 Confidential Information of Clients

GCT maintains the confidential information of its clients, and all GCT personnel, including committee members, contractors, or other individuals acting on GCT's behalf, shall keep confidential all information obtained or created during GCT's activities, except as required by law. Confidential information includes data, materials, products, technology, computer programs, specifications, manuals, business plans, software, marketing plans, business plans, financial information, and other information disclosed or submitted, orally, in writing, or by any other media generated by or for the client. GCT will inform the clients, in advance, of the information it intends to place in the public domain. To ensure confidentiality, GCT requires the signing of the Employee/Consultant Confidentiality and Disclosure form. GCT specifies in its contract any information to be displayed in the public domain. GCT will collaborate with clients or representatives of clients in clarifying the client's request and in monitoring GCT's performance in relation to the work performed, provided GCT ensures confidentiality to other clients.

4.5.2 Legal Documents

Except as required in ISO/IEC 17065, ISO/IEC 17025, TNI Standard or by law, information gained during certification activities about a particular product or applicant shall not be disclosed to a third party without the written consent of the applicant and client. Where the law requires information to be disclosed to a third party, the applicant and client shall be informed of the information provided as permitted by the law.

4.5.3 Additional Client Information

During its certification activities, GCT may obtain information from other sources than the client. Any information, except as noted in 4.5.1 and 4.5.2, will be treated as confidential.

4.6 Publicly Available Information

GCT shall provide information on the company website, <http://www.gctla.com>, and update them as necessary on the following topics.

- a) Certification Authority, Certification System, Evaluation Procedures, Quality Manual
- b) Financial Support and Fees
- c) Rights and Duties of Applicants
- d) Complaints and Appeals

4.7 Procurement

4.7.1 Procurement Policy

GCT's Procurement Procedure sets forth the conditions for the selection, reception, and storage of supplies, and for vendor selection.

4.7.2 Purchased Supplies

Purchased supplies shall be inspected, logged into the GCT supply book. GCT has the proper chemicals and reagents listed for each SOP. Each purchased chemical and reagent shall be checked against the SOP.

4.7.3 Documents

All documents associated with the purchase of supplies shall be filed electronically and made available upon request in accordance with GCT's Document Control and Retention Policy.

4.7.4 Critical Supplies

GCT shall maintain a list of vendors who stock supplies and services critical to the quality of testing and maintain an approved list.

4.8 Agreement with ANSI

GCT warrants that it will fully comply with its Program documents submitted to ANSI under the Program and agrees to promptly inform ANSI of any substantive changes relevant to its accreditation, including with respect to its status, operation or Program Documents, and further including:

- a) its legal, commercial, ownership or organizational status.
- b) the organization, top management, and key personnel.
- c) main policies.
- d) resources and premises.
- e) scope of accreditation; and
- f) other such matters that may affect the ability of the GCT to fulfill requirements for accreditation.

5.0 STRUCTURAL REQUIREMENTS

5.1 Organization Structure and Top Management

5.1.1 Certification and Impartiality

Participants in GCT certification testing and design evaluation activities must sign a contract to commit to being free from any commercial, financial and other internal and external pressures that may adversely affect the quality of their work. While GCT program goals include objectives for the broad commercialization of residential wastewater treatment systems, employee salaries and promotion are not dependent upon the commercial or technical success of any specific commercial activity. GCT employees are evaluated on a yearly basis pursuant to performance-based criteria.

5.1.2 Organizational Structure

GCT maintains an organization chart and job descriptions. The organizational chart can be found in Annex A.

5.1.3 Organizational Responsibility

The GCT organization chart and job descriptions identify the authority and responsibility for each of the following:

5.1.3.1 GCT Program Manager (Certification and Laboratory)

- a) The GCT Program Manager is responsible for the GCT's management system and maintaining the integrity of the management system when changes to the management system are planned and implemented.
- b) The Program Manager along with input from GCT employees, manufacturers, and other ANSI accredited third party certifiers, formulates the policies and procedures relating to the operation of the certification body.
- c) The Program Manager, along with the QA/QC Manager, is responsible for personnel competence requirements.
- d) The Program Manager supervises the implementation of all policies and procedures relating to new certifications.
- e) The Program Manager is responsible for the supervision of the finances of the certification body.
- f) The Program Manager, along with the QA/QC Manager, maintains the confidential files.
- g) The Program Manager is responsible for all contractual arrangements.

- h) The Program Manager is responsible for the provision of adequate resources for certification activities.
- i) The Program Manager shall ensure that the personnel are aware of the relevance and importance of their activities and how they contribute to the management system.
- j) The Program Manager is responsible for the decision on certification and shall use the Standards as the technical basis for all evaluation reports, test reports, and for granting certification.
- k) The Program Manager is responsible for technical performance and quality management of all testing and evaluation as defined in by ISO/IEC Guide 17065, ISO/IEC 17020, ISO/IEC 17021, and ISO/IEC 17025.
- l) The Program Manager is responsible for certification requirements. Certification requirements are referenced in GCT's Normative References and are developed by entities accredited by the American National Standards Institute (ANSI). NSF International has published numerous standards for residential wastewater and wastewater components.
- m) The Program Manager appoints an employee or consultant to be responsible for the evaluation process.
- n) The Program Manager shall form a Complaint Appeals Committee to manage complaints filed against Manufacturers, pursuant to GCT's Quality Procedure for Complaints, Disputes, and Appeals Documentation. The Program Manager shall appoint three qualified and impartial members to the committee.
- o) The Program Manager is a required signatory for all certification reports.
- p) The GCT Program Manager is responsible for responsiveness to complaints and appeals.
- q) The Program Manager shall meet the appropriate requirements as specified in Annex B of this Quality Manual.

5.1.3.2 GCT QA/QC Manager (Certification Program)

- a) The GCT QA/QC Manager shall perform all the duties of the GCT Program Manager in his absence.
- b) The Quality Assurance Manager is responsible for the review of the data and the data integrity process.
- c) The QA/QC Manager shall have functions independent of the certification functions.
- d) The QA/QC Manager shall serve as the focal point for QA/QC and be responsible for oversight and/or review of quality control data.

- e) The QA/QC Manager shall be able to evaluate data objectively and perform assessments with outside (e.g., managerial) influence.
- f) The QA/QC Manager shall have documented training and/or experience in QA/QC procedures and GCT's certification quality system; and
- g) The QA/QC Manager shall have a general knowledge of the analytical methods for which data review is performed; and
- h) The QA/QC Manager shall arrange for or conduct internal audits
- i) The QA/QC Manager shall monitor corrective actions; and
- j) The QA/QC Manager shall be responsible for training and record the date personnel are approved for performing tests and inspections.
- k) The QA/QC Manager shall be familiar with all the applicable Standards used by GCT and their respective requirements.
- l) The QA/QC Manager shall be a co-signatory on all certification reports.

5.1.3.3 The Technical Manager & QA/QC Manager (Laboratory)

- a) The GCT Technical Manager shall exercise actual day-to-day supervision of laboratory operations for the appropriate fields of accreditation and reporting of data; and
- b) The QA/QC Manager shall be responsible for GCT's Laboratory Quality Manual.
- c) The QA/QC Manager shall notify laboratory management of deficiencies in the quality system; and
- d) The QA/QC Manager shall have documented training and/or experience in QA/QC procedures and the laboratory's quality system; and
- e) The QA/QC Manager shall meet the appropriate requirements as specified in Annex B.
- f) The Technical Manager shall be experienced in the fields of accreditation for which the laboratory is seeking accreditation; and
- g) The Technical Manager shall have duties that include both the monitoring standards of performance in quality control and quality assurance and monitoring the validity of the analyses performed and data generated in the laboratory to assure reliable data; and,
- h) The Technical Manager is an authorized signer of laboratory reports.
- i) The Technical Manager shall not be the technical manager of more than one laboratory; and

- j) In the event the Technical Manager is if absent for a period exceeding fifteen (15) consecutive calendar days, GCT shall designate another full-time staff member meeting the qualifications of the technical manager to temporarily perform this function. If this absence exceeds thirty-five (35) consecutive calendar days, the primary accreditation body shall be notified in writing.
- k) The Technical Manager shall meet the appropriate requirements as specified in Annex B.
- l) The GCT Technical Manager and QA/QC Manager are combined into one position.

5.1.3.4 GCT Laboratory Manager

- a) The GCT Laboratory Manager is responsible for the day-to-day operations of the laboratory.
- b) The GCT Laboratory Manager shall be familiar with the regulatory requirements specific to the lab; and ensures all users are following those standards.
- c) The GCT Laboratory Manager oversees laboratory safety and ensures that the laboratory remains in compliance with all local, state, and federal regulations.
- d) The GCT Laboratory Manager ensures the laboratory is clean and kept in an orderly manner.
- e) The GCT Laboratory Manager trains personnel in teaching techniques and safe laboratory practices.
- f) The GCT Laboratory Manager is an authorized signer of laboratory reports.
- g) The GCT Laboratory Manager is responsible for analysis of results, including statements of nonconformity or opinions and interpretations.
- h) The GCT Laboratory Manager is responsible for reporting, reviewing, and authorizing laboratory results.

5.1.3.4 GCT Engineering Manager

- a) The GCT Engineering Manager shall perform engineering work regarding the operation and design of certified treatment systems.
- b) The Engineering Manager shall perform analysis of the data relating to a specific Standard and making a recommendation whether the data conforms to the requirements of the Standard.
- c) The Engineering Manager shall be familiar with all the applicable Standards used by GCT and their respective requirements.

- d) The Engineering Manager shall meet the appropriate requirements as specified in Annex B.

5.1.3.5 GCT Laboratory Technician and Field Technician

- a) The GCT Laboratory and Field Technician shall be responsible for all the activities of the laboratory and field operations.
- b) The GCT Laboratory and Field Technician shall maintain the records of the laboratory both manually and electronically, including, but not limited to data results, chains of custody, calibration results, repairs, visitor logs, equipment installation and laboratory supplies.
- c) The GCT Laboratory and Field Technician shall be familiar with all the applicable Standards used by GCT and their respective requirements.
- d) The GCT Laboratory and Field Technician shall meet the appropriate requirements as specified in Annex B.

5.1.4 Committees

GCT currently has no standing committees. However, in the event of a complaint, an Appeals Committee may be formed as per GCT's Quality Procedure for Complaints, Disputes, and Appeals Documentation.

5.2 Mechanism for Safeguarding Impartiality

5.2.1 Mechanism

GCT safeguards impartiality using its Quality Manual, Quality Procedures, particularly the Internal Audit and Management Review, and Quality Forms. GCT identifies risks to its impartiality on an ongoing basis with the Quality Procedure on Impartiality. This includes those risks that arise from our activities, from our relationships, or from the relationships of our personnel; however, such relationships do not necessarily present a certification body with a risk to impartiality. It is understood that a relationship that threatens the impartiality of the certification body can be based on ownership, governance, management, personnel, shared resources, finances, contracts, marketing (including branding), and payment of a sales commission or other inducement for the referral of new clients.

- a) GCT is impartial as required by ISO/IEC 17065, ISO/IEC 17020, ISO/IEC 17021, and ISO/IEC 17025. GCT is also impartial pursuant to the data integrity requirements of the TNI Standard. For every service offered by GCT, there is a unique procedure for working with all the applicants and a universally applicable Confidentiality and Disclosure Agreement.
- b) Employees and consultants shall disclose to GCT any commercial interest or financial interest outside of their association with GCT in connection with any manufacturers associated with GCT.
- c) An employee's or consultant's failure to disclose a relationship with a client will result in immediate termination and a possible suspension of the certification of the manufacturer.

5.2.2 Documentation of Impartiality

GCT documents its impartiality by having its employees sign the following documents:

- a) Management Review
- b) Confidentiality and Disclosure Agreement
- c) Internal Audit Random Impartiality Audits

5.2.3 Impartiality of Management

In the event management is not impartial in GCT's scheme, employees shall take independent action to preserve impartiality while respecting the client's right to confidentiality. Such independent may include, but is not limited to, reporting to other management, regulators, auditors, and accreditors. Additionally, an input from management in conflict with the impartiality requirements of ISO/IEC 17065 shall not be followed.

5.2.4 Interested Parties

During the internal audit, GCT shall identify and invite the comments of significantly interested parties. Interested parties may include clients, clients of clients, manufacturers, and governmental regulatory bodies.

6.0 RESOURCE REQUIREMENTS

6.1 Certification Body and Laboratory Personnel

6.1.1 General

6.1.1.1 Sufficient Personnel

GCT clearly documents job descriptions, duties, and the minimum qualifications for each job at GCT to ensure sufficient personnel are in place to cover its certification and laboratory activities.

6.1.1.2 Qualified and Competent Personnel

GCT testing and evaluation personnel are competent for the functions they perform, including making required technical judgments by completing an apprenticeship under a GCT employee or prior experience. The Program Manager leads the GCT quality organization and shall be the sole judge of an employee's competence. The Program Manager and Laboratory Manager shall communicate to all personnel their duties, responsibilities, and authorities.

6.1.1.3 Confidentiality

All GCT personnel, including committee members, shall sign a confidentiality and disclosure agreement. Except as required in ISO/IEC 17065 and ISO/IEC 17025 or by law, information gained during certification activities about a particular product or applicant shall not be disclosed to a third party without the written consent of the applicant and client.

6.1.1.4 Additional Personnel Requirements

The applicable requirements for the Technical Manager are given in Annex B.

6.1.1.5 Data Integrity Training

Data integrity training shall be provided for pursuant to the Data Integrity Procedure.

6.1.2 Management of Competence for GCT Certification Personnel

6.1.2.1 Training of Personnel

GCT has procedures to ensure the competencies of its personnel. The procedures require GCT to:

- a) Maintain job descriptions with competence requirements for all its employees.
- b) Select the most qualified employees.
- c) Establish annual training goals and maintains a training record for personnel, including employees and contract personnel.
- d) Record the training information in the Training Documentation Log.
- e) Maintain a functional organization chart for authorization in the certification process and laboratory process.
- f) Monitor the performance of personnel with annual reviews

6.1.2.2 Training Records

GCT maintains the following records on all personnel involved in the certification process:

- a) name and address
- b) organization affiliation and position held
- c) educational qualification and professional status
- d) experience and training in each field of the testing and design evaluation
- e) training log
- f) personnel evaluation
- g) authorizations held at GCT
- h) date of the most recent updating of the employee records

6.1.3 Contract with the Personnel

GCT requires all employees and consultants involved in the certification process to sign Confidentiality and Non-Disclosure Agreements by which they commit themselves to the following:

- a) To comply with all GCT's rules, especially those regarding confidentiality
- b) To disclose any prior and/or present relationship with any clients or client's consultancy
- c) To reveal any situation known to them to be a conflict of interest regarding the certification activities

6.2 Resources for Evaluation

6.2.1 Internal Resources

When GCT performs evaluation activities, either with GCT personnel or consultants, the personnel shall meet the applicable requirements of ISO/IEC 17025 and TNI Standard for laboratory analysis, ISO/IEC 17020 for inspection, and ISO/IEC 17021 for management system auditing.

6.2.2 External Resources

6.2.2.1 Outsourcing

GCT only outsources evaluation activities to independent bodies that meet the applicable requirements of ISO/IEC 17025 and TNI Standard for laboratory analysis, ISO/IEC 17020 for inspection, and ISO/IEC 17021 for management system auditing.

6.2.2.2 Outsourcing to Non-independent bodies

GCT does not outsource to non-independent bodies.

6.2.2.3 Contract for Outsourcing

GCT shall have a legally binding contract with any independent body that provides outsourced service.

6.2.2.4 Responsibility for Outsourcing

GCT has developed Quality Procedures to:

- a) Accept responsibility for all activities outsourced.
- b) Ensure the outsourced body is impartial.
- c) Assess and monitor all outsourced activities.
- d) Maintain a list of approved consultants.
- e) Implement corrective action for breaches of contract or other issues.
- f) Inform the client in advance of using a consultant, in the event the client may object.

7.0 PROCESS REQUIREMENTS

7.1 General

7.1.1 Certification Scheme

GCT certifies to the NSF/ANSI Standards referenced in Section 2.0 of this document. GCT has developed Quality Procedures, Quality Forms, and SOP's for its certification activities relating to these Standards.

7.1.2 Certification Requirements

GCT certifies pursuant to the Standards referenced in Section 2 of this document and the GCT Quality Procedures and SOP's for the Standards.

7.1.3 Certification Explanations

The criteria contained in the STANDARDS require no explanation as to the certification theme.

7.1.4 Laboratory Capabilities

It is GCT's laboratory's responsibility to conduct its activities to meet ISO/IEC 17025 requirements and to meet the needs of clients, regulatory authorities, or others providing recognition. The GCT Laboratory shall establish and maintain procedures for the review of laboratory SOP's, requests, and contracts. GCT personnel shall establish:

- a) Requirements, including the methods to be used, are adequately defined, documented, and understood.
- b) The laboratory has the capability and resources to meet the requirements.
- c) When GCT uses outside laboratories, the requirements of 6.6.2 of GCT's Quality Manual are applied, and GCT advises the client of the specific laboratory activities to be performed by the outside laboratory and gains the client's approval.
- d) The appropriate test and/or calibration is selected and can meet the client's requirements.
- e) In the event a client requests a method GCT considers inappropriate or out of date, GCT shall inform the client.

- f) When the client requests a statement of conformity to a specification or standard for the test (e.g., pass/fail, in-tolerance/out-of-tolerance), the specification or standard and the decision rule shall be clearly defined. Unless inherent in the requested specification or standard, the decision rule selected shall be communicated to, and agreed with, the client.

7.2 Application

GCT requires an Application for Certification before GCT can initiate the certification process. The application is available on the website or by request from GCT. The application must be signed by a duly authorized representative of the client, in which the following information is specified:

- a) Corporate entity, name, address, and legal status
- b) Description of the residential wastewater treatment system or component
- c) Scope of certification services
- d) An agreement by the client to provide any information needed for evaluation of products to be evaluated and/or tested and agrees to comply with the requirements for certification including but not limited to the Standards, GCT's Quality Manual, and all contractual requirements included in the Contract for Standard Performance Evaluation
- e) An agreement the client will adhere to the policies and procedures of GCT

7.3 Application Review

7.3.1 Review of Application Information

GCT conducts a review of the application using GCT's Quality Procedures and Quality Forms to determine:

- a) The client information is sufficient to conduct the certification process
- b) Any differences in understanding between the GCT and the client is resolved
- c) The scope of the certification is defined
- d) GCT has the means available to perform the certification
- e) GCT has the competence and capability to perform the certification activity

7.3.2 Certification of Products with no prior experience

GCT has Quality Procedures and Quality Forms to identify when a client's request for certification includes a scope or product for which GCT has no prior experience. The Program Manager, after consultation with the Lab Manager, shall then decide as to whether GCT has the competence to evaluate the product.

7.3.3 Certification Justification of a Product

GCT shall maintain records of its competence and capability for all certification activities. The information shall be readily available and shall include the date on when the competence is confirmed.

7.3.4 Declining Certification of a Product

GCT reserves the right to decline to undertake a specific certification if it lacks competence or the capability for the certification activity.

7.3.5 Certification of Similar Products

GCT shall consider past certifications or certifications granted to other clients and may omit certain activities in the certification process if it does not compromise the certification process. GCT shall document these omissions pursuant to its Quality Procedures and provide justification if requested.

7.4 Evaluation

7.4.1 Evaluation Plan

GCT, pursuant to its Quality Procedures and Quality Forms, develops an evaluation plan for all certification activities.

7.4.2 Assignment of Personnel

GCT assigns personnel to each activity.

7.4.3 Documentation for Evaluation

GCT uses Quality Forms to ensure the necessary information is available for performing the evaluation tasks.

7.4.4 Evaluation Process

Pursuant to GCT's Quality Procedures, GCT shall evaluate the product in accordance with the evaluation plan to the criteria of the Standard.

7.4.5 Evaluation Results

GCT only relies on the evaluation results related to the certification prior to the application for certification and ensures the results are in accordance with certification scheme.

7.4.6 Evaluation Non-Conformities

GCT shall inform the client of all non-conformities documented by the evaluation process.

7.4.7 Evaluation Process with Non-Conformities

GCT shall allow the client to address any non-conformity and continue the evaluation process.

7.4.8 Documentation of Evaluation Process with Non-Conformities

The evaluation process shall continue pursuant to GCT's Quality Procedures.

7.4.9 Documentation of Evaluation Activities Prior to Review

GCT shall document all the evaluation activities prior to the evaluation review.

7.4.10 Control of Nonconforming Laboratory Testing

GCT's Control of Nonconforming Work Procedure shall be implemented when any aspect of its testing or accreditation work does not conform to its own procedures or the agreed requirements of the client.

7.4.10.1 Policy and Procedure

GCT's Control of Nonconforming Testing Procedure shall:

- a) Define responsibilities and authorities for the management of nonconforming work are designated and actions, including halting of work and withholding of test reports, are defined and taken when nonconforming work is identified.
- b) Institute an evaluation of the significance of the nonconforming work.
- c) Initiate a correction immediately, together with any decision about the acceptability of the nonconforming work.
- d) Notify the client and recall the work, if necessary.
- e) Define the responsibility for authorizing the resumption of work.

7.4.10.2 Implementation of Corrective Action

When the evaluation indicates the nonconforming work could recur or there is doubt regarding the laboratories operations with its own policies and procedures, the Corrective Action Procedure should be promptly followed.

7.5 Review

7.5.1 Certification Review

GCT assigns one person to review the certification information and results who was not involved in the evaluation. The evaluator makes a recommendation to the GCT Program Manager regarding certification.

7.5.2 Documentation of Review

The Program Manager, after reviewing the documentation, makes a recommendation regarding certification.

7.6 Certification Decision

7.6.1 Responsibility for Certification

GCT is responsible for all decisions on certification. GCT shall make decisions on certification based exclusively on the information gathered during the evaluation process and any other relevant information as determined exclusively by GTC. Should GCT discover information relevant to the certification outside of the certification process, the applicant shall have the opportunity to comment on the information.

7.6.2 Personnel Responsible for Certification

The GCT personnel responsible for the evaluation shall not be involved in making the decision on certification.

7.6.3 Employment by GCT

The person making the decision regarding certification shall be employed by GCT.

7.6.4 Organization Control

GCT is 100% owned by the Program Manager and managed by a Board of Directors.

7.6.5 Personnel with entities under Organizational Control

GCT is not part of a larger entity.

7.6.6 Declining to grant certification

- a) In the event the decision by the GCT Program Manager is not to grant certification, GCT shall specifically identify the reasons for the decision. GCT shall allow the client to correct the non-conformity and continue testing pursuant to GCT's Quality Procedures.
- b) In the event the client requests to see GCT's laboratory results, including the QA/QC data, GCT will make the data available in a report for the client, including the calibration data.

7.7 Certification Documentation

7.7.1 GCT's Certification Documents

GCT shall provide the client with a GCT's Certification Certificate with the following information:

- a) GCT's name and address
- b) The date the certification was granted
- c) The name and address of the client
- d) The scope of the certification
- e) The expiration of the certification
- f) Any other information required by the certification process, including laboratory data

7.7.2 Signing of Certification Documents

The certification certificate shall be signed by the GCT Program Manager and the Quality Assurance Officer

7.7.3 Timing of Release of Certification Documentation

GCT will only issue certification documents after the following:

- a) The decision to grant or extend the scope of certification has been made
- b) The certification requirements have been fulfilled
- c) The certification certificate has been signed

7.8 Directory of Certified Products

Pursuant to the Standards, GCT maintains all the information for its certified products on GCT website. GCT shall provide any information regarding the validity of a certification by request, but provides the following information on its website:

- a) Identification of the Product
- b) The standard to which the product has been certified
- c) Identification of the client

7.9 Surveillance

7.9.1 Annual Compliance Audits

GCT's scope of certification includes annual compliance audits. The audits determine the continuing compliance by the Client with the program standards and policies.

7.9.2 Evaluation, Review, and Certification

GCT does not evaluate, review, or certify during annual compliance audits.

7.9.3 Compliance Audits and Certification

Annual compliance audits determine the continuing compliance by the Client with the program standards and policies. A GCT inspector will visit the facility in the presence of the Client and conduct an audit using the Manufacturer's Audit Checklist. The inspector needs to have access to all records, product literature, on-site tanks, personnel, and all other areas of the facility, except those where safety does not permit. The inspector uses inspection worksheets to guide the process including the In-Plant Audit Form, the Equipment Evaluation Form, Authorized Representative Inspection Report, Site Visit Inspection Report, and the Narrative Page. If a Supplier is found in non-compliance with the requirements given by GCT's ANSI certification program, the GCT inspector will note the non-compliance on the Corrective Action form and the Supplier will be given an opportunity to correct deficiencies. The auditor may or may not choose to return for a second audit. More information regarding annual compliance audits can be found in GCT's procedure for New and Continuing Compliance Reports.

7.9.4 Annual Compliance Audits for Process or Service

GCT does not certify processes or services.

7.10. Changes Affecting Certification

7.10.1 Changes in Standards

When Standards change, GCT shall immediately inform the client of the change. The client must implement the changes in the Standard in time determined by GCT's Quality Procedures. Gulf Coast Testing will review the implemented changes and will evaluate the changes as per GCT's Evaluation Procedure

7.10.2 Changes by Client

Changes initiated by the client shall be evaluated pursuant to GCT's Quality Procedures.

7.10.3 Implementation of Changes affecting certification

GCT shall perform the following actions for all changes in the certification Standard or changes requested by the client:

- a) Evaluation
- b) Review
- c) Decision
- d) Issuance of Certification Documentation
- e) Performance of Annual Compliance Audits

7.11 Termination, reduction, suspension, or withdrawal of certification

7.11.1 Action on Nonconformance

GCT has procedures to re-evaluate certification in the event of changes significantly affecting the products design or specification, or for changes in Standards to which compliance of the product is certified, or if GCT obtains information indicating the product may no longer comply with the requirements of the standard to which it is certified.

7.11.2 Action on Nonconformance with Evaluation

GCT's procedures for termination, reducing scope, or withdrawal include the requirements of 7.4, 7.5, and 7.6.

7.11.3 Termination or Withdrawal of Certification

If certification is terminated, GCT will issue a Revocation of Certified Mark® to the client pursuant to its procedures.

7.11.4 Suspension of Certification

GCT does not suspend certification. GCT only terminates the certification pursuant to its procedures.

7.11.5 Resolution of Suspension of Certification

GCT does not suspend certification. GCT only terminates the certification pursuant to its procedures.

7.11.6 Reinstatement of Suspended Certification

GCT does not suspend certification. GCT only terminates the certification pursuant to its procedures.

7.12 Records

7.12.1 Records Retention Policy

GCT's records policy is outlined in GCT's Document Control and Retention Procedure and supports its certification scheme and the requirements of ISO/IEC 17065, ISO/IEC 17025, and the TNI Standard.

GCT maintains three types of documents in its quality system:

- a) QA Documents include all quality system documents such as this manual, the Quality Procedures Manual with all the associated instructions and forms, and SOP's.
- b) Project Documents include all documents associated with a particular certification test or design evaluation and the associated laboratory documents including bench sheets.
- c) Correspondence includes communication between GCT members and clients.

7.12.2 Confidentiality of Records

Pursuant to its records policy, GCT keeps some records confidential.

- a) For electronic records, confidential records are stored on the cloud and only authorized GCT employees have access to the records.
- b) For paper records, the confidential records are stored in locked file cabinets in a locked office and only authorized GCT personnel have access to the records.

7.12.3 Re-evaluation of Certification Records

GCT keeps all records for re-evaluation for the required re-evaluation pursuant to the Standard or a minimum of seven years. Upon completion of a project, the electronic documents, organized in project files, are copied into an archiving area on the disk. A cyclic backup is conducted as necessary and the backup copies are maintained on a cloud server. Long-term archiving is the responsibility of the GCT Program Manager who stores test and project records in accordance with the Standards. Additionally, GCT shall follow all legal requirements (state and federal) regarding the control of documents.

7.12.4 Correcting Mistakes in Records

Mistakes in records are corrected pursuant to GCT's Document Control and Retention Procedure.

7.13 Complaints and Appeals

7.13.1 Complaint and Appeals Process

A complaint and appeal process is available to all clients to fairly and equitably handle disputes.

7.13.2 Complaints and Appeals Applicability

GCT, upon receiving a complaint, shall confirm if the complaint is within GCT's scope of certification or laboratory activities. Upon determination the complaint relates to those activities, GCT shall address the complaint pursuant to GCT's Quality Procedure for Complaints, Disputes, and Appeals Documentation.

7.13.3 Formal and Informal Complaints and Appeals

GCT recognizes two types of complaints and appeals, formal and informal. A formal complaint/appeal is submitted in writing or using the complaint form on the GCT website. Informal complaints are complaints received verbally. GCT will document and investigate all complaints/appeals, formal and informal. Informal complaints/appeals are investigated as deemed appropriate by GCT personnel. Formal complaints/appeals are acknowledged in writing and managed pursuant to GCT's Quality Procedure for Complaints, Disputes, and Appeals Documentation.

7.13.4. Information for Complaints and Appeals

GCT shall be responsible for gathering and verifying all necessary and available information to process the complaint or appeal to a decision.

7.13.5. Decisions on Complaints and Appeals

The decision resolving the complaint or appeal shall be reviewed and approved by the GCT Program Manager.

7.13.6. Conflicts of Interest

Except for the GCT Program Manager and Quality Assurance Officer, GCT personnel who have provided consultancy to a client or been employed by the client shall not be used by the GCT to investigate or review a complaint for two years following the end of the consultancy or employment.

7.13.7. Notice

GCT acknowledges the outcome of all formal complaints, and the outcomes are acknowledged pursuant to GCT's Quality Procedure for Complaints, Disputes, and Appeals Documentation.

7.13.8. Notification of Outcome

In the event of an appeal, the GCT Program Manager shall follow the procedures in GCT's Quality Procedure for Complaints, Disputes, and Appeals Documentation. GCT shall respond to both the complainant and appellant in writing with the results of the appeal.

7.13.9. Resolution

Upon resolution of the complaint or appeal, GCT shall perform all action necessary to resolve the complaint or appeal.

8. MANAGEMENT SYSTEM REQUIREMENTS

8.1 Options

8.1.1 “Option A” CB

Pursuant to ISO/IEC 17065, GCT is an “Option A” Certification Body. GCT’s written Quality Procedures, Quality Forms, and SOP’s are consistent with fulfillment of the requirements of ISO/IEC 17065, ISO/IEC 17025, and TNI Standard.

8.1.2 Management System Information

GCT’s management system addresses the following:

- a) General Management System Documentation
- b) Control of Documents
- c) Control of Records
- d) Management Review
- e) Internal Audit
- f) Corrective Actions
- g) Preventive Actions

8.1.3 “Option B” CB

GCT has not established a management system in accordance with requirements of ISO 9001.

8.2 General Management System Documentation

8.2.1 Policies and Objectives

It is the policy of GCT to achieve and maintain the highest standard of quality in all aspects of its work. The purpose of the GCT quality system is to:

- a) Ensure the requirements of ISO 17065 and ISO 17025 are met daily for all certification and testing activities for which GCT accreditation is held.
- b) Ensure the needs of clients, the regulatory authorities and any other organizations that provide recognition are fully understood and met.
- c) Ensure the test methods selected are up to date and fully validated as fit for purpose to ensure the accuracy and reliability of our test results.

GCT has written Quality Procedures, Quality Forms, and SOP's that establish, document, and maintain policies and objectives of the ISO/IEC 17065, ISO/IEC 17025 and GCT's certification scheme. The GCT Program Manager ensures that the management system is understood, implemented, and maintained at all levels of the operations. The documents are available to all personnel on the website. The Program Manager shall update the website when any changes to the Quality Manual have been made.

The objectives of the quality management system are to:

- a) Ensure the continued development, implementation, and maintenance of the quality system and to continually seek improvements in the effectiveness of the quality system.
- b) Report results accurately and unambiguously in a timely manner; to seek improvements in the service provided to clients; to continually review the determinations offered to all clients to continue to meet the needs of the testing and certification industry.
- c) Meet client requirements in terms of turn-around time, sample collection, reliability of service and reporting.
- d) Ensure tests are performed by suitably trained and qualified staff and provide opportunities for staff to extend their knowledge and competency and gain relevant professional qualifications.
- e) Ensure equipment used is fit for purpose, properly maintained, calibrated, and where possible, measurements are traceable to recognized standards.
- f) To challenge the business to seek improvements in the equipment, its capability and methodology used.
- g) Ensure full traceability throughout the sample handling process and to ensure sample handling procedures and environmental conditions do not affect the results; to look for improvements in our procedures and facilities to improve organization and workflow.
- h) Use internal audits, external proficiency, and other checks to ensure the quality system continues to comply with requirements; to ensure problems are investigated promptly, the root cause established, and effective action taken to prevent a recurrence.
- i) Seek to improve communication (internal and with clients) to ensure information is made available as rapidly and as accurately as possible to those who need it, while ensuring confidentiality of the client is maintained.
- j) Monitor subcontractors and suppliers to ensure quality standards are maintained in line with GCT expectations.
- k) Ensure laboratory activities are undertaken impartially and risks to impartiality are identified and minimized.

- l) Continually assess risks and opportunities in relation to laboratory activities to give assurance that:
 - 1. the management system is achieving its intended results.
 - 2. opportunities are enhanced to achieve the purpose and objectives of the laboratory.
 - 3. undesired impacts and potential of failures are prevented or reduced.
 - 4. the laboratory achieves improvement.
- m) Ensure the system is maintained when changes to the management system are planned and implemented

8.2.2 Commitment to Management System

The GCT Program Manager evidences his commitment to the development and implementation of the management system by demanding strict adherence to the procedures and instructions of the system. The GCT Program Manager further evidences his commitment to a quality management system by periodically reviewing and revising the Quality Manual, Quality Procedures, and Quality Forms to meet the objectives of ISO/IEC 17065 and ISO/IEC 17025. GCT shall strive to continually improve the effectiveness of its management system using the Quality Policy, Quality Procedures, Internal Audits, Management Reviews, Corrective Actions, and Preventive Actions. The GCT Program Manager shall communicate to the entire organization the importance of meeting client requirements as well as statutory and regulatory requirements.

8.2.3 Responsibility to Maintain Management System

8.2.3.1 Program Manager

- a) Ensure that processes and procedures for the management system are established, implemented, and maintained.
- b) Continually evaluate the performance of the management system and any need for improvement.
- c) Ensures the integrity of the management system is maintained when changes to the management system are planned and implemented.
- d) Communication

8.2.3.2 Laboratory Manager

- a) Work with the Program Manager to ensure that processes and procedures for the management system are established, implemented, and maintained; and,

- b) identification of deviations from the management system or from the procedures for performing laboratory activities.
- c) initiation of actions to prevent or minimize such deviations.
- d) reporting to Program Manager on the performance of the management system and any need for improvement.
- e) Ensures the integrity and effectiveness of laboratory activities.
- f) Ensures communication takes place with the Program Manager regarding the effectiveness of the management system and the importance of meeting clients' and other requirements.
- g) Consider the risks and opportunities associated with laboratory activities and plan:

8.2.4 Documentation of Management System

GCT's Quality Procedures, Quality Forms, and SOP's are related to the fulfillment of the requirements of ISO/IEC 17065 and ISO/IEC 17025.

8.2.5. Access to Documents

All GCT employees have access to the documents of the quality management system.

8.3 Control of Documents

8.3.1 Records Retention Procedure

GCT has a Document Control and Retention Procedure for the control of documents and related information for the fulfillment of ISO/IEC 17065 and ISO/IEC 17025.

8.3.2 Records and Documents Policy

The Document Control and Retention Procedure defines controls needed to:

- a) Approve documents for adequacy prior to issue; and
- b) Review and update documents as necessary and re-approve documents; and
- c) Ensure that changes and the current revision status of documents are identified; and
- d) Ensure that relevant versions of applicable documents are available at points of use; and
- e) Ensure that documents remain legible and readily identifiable; and
- f) Ensure that documents of external origin are identified, and their distribution controlled; and

- g) Prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.

8.4 Control of Records

8.4.1 Records and Documents Control Policy

GCT has a Document Control and Retention Procedure for the control of documents and related information for the fulfillment of ISO/IEC 17065, ISO/IEC 17025 and the TNI Standard.

8.4.2 Records and Documents Retention Policy

The Document Control and Retention Procedure controls the retention and disposition of all documents with contractual and legal obligations and ensures confidentiality of the documents.

8.4.3 Laboratory Technical Records

8.4.3.1 Record Keeping

GCT retains records of original observations, derived data, and sufficient information to establish and audit trail, calibration records, staff records and a copy of each test report or calibration certificate issued for seven years or as required by local, state or federal laws and regulations.

- a) The records shall contain sufficient information to facilitate, if possible, identification of factors affecting the uncertainty and to enable the test or calibration to be repeated under conditions as close as possible to the original. The records shall include the identity of personnel responsible for the sampling, performance of each test and/or calibration and checking of results. The technical records shall include the date and the identity of personnel responsible for each laboratory activity and for checking data and results. Original observations, data and calculations shall be recorded at the time they are made and shall be identifiable with the specific task.
- b) GCT shall ensure that amendments to technical records can be tracked to previous versions or to original observations. Both the original and amended data and files shall be retained, including the date of alteration, an indication of the altered aspects and the personnel responsible for the alterations.

8.4.3.2 Recording Data

Observations, data, and calculations shall be recorded at the time they are made and shall be identifiable to the specific task. GCT does utilize a LIMS data system. GCT stores the information collected electronically and has access to the data needed to perform laboratory activities.

- a) The GCT Laboratory data is protected from unauthorized access by password.
- b) The GCT Laboratory data is safeguarded against loss by storing the information on the cloud.
- c) The GCT Laboratory data is collected in a manner which promotes accuracy.
- d) The GCT Laboratory data is maintained in a manner that ensures the integrity of the data and information.
- e) In the event of a recording failure, the GCT Laboratory has a data management SOP for immediate and appropriate corrective action.

8.4.3.3 Errors in Records

When errors occur in manual written records, each error shall be crossed out. Errors shall not be erased, made illegible, or deleted, and the GCT employee making the correction shall initial the entry. When errors occur in computerized records, a note is made of the change and a reason for the change.

8.4.3.4 Manuals

All manuals are available on the GCT cloud document system.

8.4.3.5 Calculations

Calculations and data transfers are pursuant to GCT data management SOP.

8.4.4 Sample Collection Data Requirements

GCT shall establish a record keeping system that allows the history of the sample and associated data to be readily understood through GCT's documentation.

- a) GCT to follow the history of the sample with accurate records that document all GCT's laboratory activities including equipment, analytical methods, sample date and/or receipt, and data verification

- b) GCT retains all laboratory records for a minimum of seven years or as required by law or regulation, whichever is greater
- c) Records of reviews, including any significant changes, shall be retained. Records shall also be retained of pertinent discussions with a client relating to the client's requirements or the results of GCT's laboratory activities.
- d) GCT to make all records available to the accreditation body
- e) GCT's records stored on electronic media to be retrieved when requested
- f) GCT to access archived information with an access log
- g) GCT to retain all data necessary for the historical reconstruction including:
 - 1) Raw data and original observations
 - 2) Written description of the method and associated SOP
 - 3) Sample ID code
 - 4) Data of analysis
 - 5) Time of analysis when time critical steps are included in the analysis
 - 6) Instrumentation Identification
 - 7) Manual Calculations
 - 8) Laboratory Analyst Signatures
 - 9) All information associated with sample preparation
 - 10) Test results
 - 11) Standard and Reagent information
 - 12) Calibration Criteria, frequency, and acceptance criteria
 - 13) Data and statistical calculations
 - 14) Quality control information
 - 15) Electronic data information
 - 16) Method performance criteria
 - 17) PT results
 - 18) Records of demonstration for each analyst
 - 19) Record of names for all GCT employees signing documents
 - 20) GCT to record all data in ink
 - 21) GCT to transfer records in the event of an ownership change

8.5 Management Review

8.5.1 General

8.5.1.1 Management Review

GCT has a management review procedure to review its management system on annual intervals or as necessary to ensure the continuing suitability, adequacy, and effectiveness, including stated policies and

objectives related to the fulfillment of ISO/IEC 17065 and ISO/IEC 17025.

8.5.1.2 Annual Reviews

GCT conducts, at a minimum, annual reviews at least once per year. All records from the annual reviews are maintained pursuant to GCT's Document Control and Retention Procedure.

8.5.2 Review of Inputs to Management Review

GCT incorporates the following information into the Management Review pursuant to GCT's Management Review Procedure:

- a) Results of Internal and External Audits
- b) Feedback from clients and interested parties
- c) Feedback from Impartiality Procedure
- d) Status of Preventive and Corrective Actions
- e) Follow-Up actions from previous management reviews
- f) Fulfilment of Objectives
- g) Changes affecting the management system
- h) Appeals and complaints

8.5.3 Review Outputs

GCT uses the information from the management reviews for the following actions and decisions:

- a) Improvement of the effectiveness of the management system and its processes
- b) Improvement of the certification body related to the fulfillment of ISO/IEC 17065
- c) Identifying present and future resource needs

8.5.4 Data Integrity Investigations

All investigations resulting from data integrity issues shall be conducted in a confidential manner until completion. The investigations shall be documented, as well as any notifications made to clients receiving any affected data.

8.6. Internal Audits

8.6.1 Internal Audit Procedure

GCT has an Internal Quality Assurance Audit Procedure that fulfills the requirements of its management system, ISO/IEC 17065, and ISO/IEC 17025, and GCT's management system is effectively implemented and maintained.

8.6.2 Audit Assurance Procedure

The GCT Internal Quality Assurance Audit Procedure is planned to take into consideration the importance of the GCT's certification processes and areas to be audited, as well as the results of previous audits.

8.6.3 Audit Frequency

GCT performs an internal audit on an annual basis.

8.6.4 Audit Requirements and Outcomes

Personnel who conduct internal audits are knowledgeable in certification, auditing, and the requirements of ISO/IEC 17065 and ISO/IEC 17025.

- a) Auditors do not audit their own work.
- b) All GCT personnel are notified of the results of the audit.
- c) Any actions taken from the internal audits are implemented timely and in an appropriate manner.
- d) Any opportunities for improvement are identified

8.6.5 Notification of Clients

In the event the GCT internal audit discloses events that cast doubt on the validity of a client's results, GCT shall notify the client pursuant to GCT's internal audit procedure.

8.7 Corrective Actions

8.7.1 Corrective Actions

GCT has a Corrective Action Procedure for the identification and management of nonconformities in its certification operations.

8.7.2 Nonconformities

GCT takes actions to eliminate the causes of nonconformities to prevent recurrence. The QA/QC Manager shall determine the root cause of the nonconformity. Root cause analysis is a process by which GCT employees identify the true cause of a nonconformance.

8.7.3 Appropriateness of Corrective Actions

GCT applies corrective actions appropriate to the impact of the problems encountered.

8.7.4 Corrective Action Procedure Requirements

GCT's procedure for corrective actions shall define the following requirements:

- a) Identifying nonconformities
- b) Determining the causes of nonconformity
- c) Correcting nonconformities
- d) Evaluating the need for actions to ensure that nonconformities do not recur
- e) Determining and implementing the actions needed in a timely manner
- f) Recording the results of the actions taken and retain the records per GCT's document and retention policy
- g) Reviewing the effectiveness of corrective actions and are appropriate to the effects of the nonconformities encountered

8.7.5 Additional Audits

When the identification of nonconformities or departures casts doubts on GCT's compliance with its own policies and procedures, or compliance with ISO/IEC 17025 or TNI Standard, GCT shall schedule an internal audit as soon as possible.

8.7.6 Documented Procedures

GCT has a Corrective Action Procedure in GCT's Quality Procedures Manual stating:

- a) The GCT personnel responsible for addressing each QC data type; and
- b) The GCT personnel responsible for initiating and recommending corrective actions.

8.7.7 Systemic Error

In the event the root cause analysis in Section 8.7.2 indicates systemic error, GCT shall schedule a management review as soon as possible.

8.8 Preventive Actions

8.8.1 Preventive Actions

GCT has a Preventive Action Procedure for taking preventive actions to eliminate the causes of potential nonconformities in the certification program and laboratory activities.

8.8.2 Appropriateness of Preventive Actions

GCT evaluates the appropriateness of actions to the probable impact of the potential problem and the validity of results.

8.8.3 Preventive Action Procedure Requirements

GCT's procedure for preventive actions shall define the following requirements:

- a) Identifying potential nonconformities and their causes
- b) Evaluating the need for actions to prevent the occurrence of nonconformities
- c) Integrating and implementing the actions needed
- d) Recording the results of the actions taken
- e) Reviewing the effectiveness of the preventive action taken

9.0 TECHNICAL AND MANAGEMENT REQUIREMENTS FOR GCT LABORATORY

9.1 Laboratory Quality Manual

9.1.1 Laboratory Quality Manual Responsibility

The GCT QA/QC Manager shall have the responsibility for maintaining the GCT Laboratory Quality Manual.

9.1.2 Laboratory Quality Manual Items

- a) Document Title
- b) GCT address information
- c) Name, Address, and Phone Number for Individuals responsible for the GCT Laboratory
- d) Identification of the topics covered by the manual
- e) Identification of GCT approved signatures
- f) Signed and dated concurrence of the GCT Laboratory Manager, QA/QC Manager, and Technical Manager
- g) The objectives of the Quality System
- h) The official Quality Policy Statement
- i) A table of contents, lists of references, and list of appendices
- j) Method List and the accreditation for each method

9.1.3 Laboratory Quality Manual References

- a) All maintenance, calibration, and verification procedures used by GCT's laboratory in conducting tests:
- b) Major equipment and reference measurements standards used as well as the facilities and services
- c) Verification Practices
- d) Procedures for reporting analytical results
- e) Organization and Management Structure
- f) Document control procedures
- g) Job descriptions
- h) Measurement traceability procedures
- i) Methods used by GCT's Laboratory
- j) Work review procedures
- k) Sample handling procedures
- l) Corrective Action procedures
- m) Policy permitting departure from documented policies
- n) Complaint Procedure
- o) Confidentiality Procedure
- p) Audit Procedures

- q) Training and evaluation procedures
- r) GCT Quality Manual

9.2 GCT Quality Procedures and SOP's

GCT is committed to the development and implementation of the management system and to continually improving its effectiveness using the Management Review Procedure in 8.5 of this Quality Manual. The Program Manager and Laboratory Manager shall communicate to the organization the importance of meeting client requirements as well as statutory and regulatory requirements through the Confidentiality and Disclosure Agreement.

GCT maintains SOP's and Quality Procedures that accurately reflect all phases of current laboratory management and technical activities. The SOP's and Quality Procedures ensure the employees comply with all applicable Standards and to ensure the consistent application of GCT's laboratory activities. The Program Manager shall ensure that the integrity of the management system is maintained when changes to the management system are planned, integrated, and implemented by updating the SOP's and Quality Procedures.

A listing of each GCT SOP, corresponding Method, and the accreditation for the Method is shown in Annex C of this document and the GCT Laboratory Quality Manual.

9.3 Selection and Verification of Methods

GCT has an SOP for each method and analyte.

- a) GCT's laboratory shall use the appropriate methods and procedures for all laboratory activities and, where appropriate, for evaluation of the measurement uncertainty as well as statistical techniques for analysis of data.
- b) GCT's laboratory shall ensure that it uses the latest valid version of a method unless it is not appropriate or possible to do so. When necessary, the application of the method shall be supplemented with additional details to ensure consistent application. The GCT SOPs are readily available to all GCT employees on the GCT server.
- c) When the client does not specify the method to be used, GCT shall select an appropriate method pursuant to the Standard or analyte evaluated. GCT shall inform the client of the method chosen.
- d) Prior to introducing a new method, GCT shall pass two proficiency tests.
- e) GCT does not develop methods or deviate from its SOPs.
- f) Prior to accepting laboratory work from a client, GCT reviews the project to determine it has the appropriate facilities and resources prior to commencing the work.
- g) Each GCT SOP contains the following information:

- 1) Identification of the method
- 2) Applicable Matrix
- 3) Limits of Detection and Quantification
- 4) Scope and Application
- 5) Summary of the Method
- 6) Definitions
- 7) Interferences
- 8) Safety
- 9) Equipment and Supplies
- 10) Reagents and Standards
- 11) Sample Collection, Preservation, Shipment and Storage
- 12) Quality Control
- 13) Calibration and Standardization
- 14) Procedure
- 15) Data Analysis and Calculations
- 16) Method Performance
- 17) Data Assessment and Acceptance Criteria for QA/QC measures
- 18) Corrective Action for out-of-control data
- 19) Waste Management
- 20) Pollution Prevention
- 21) References
- 22) Tables, Diagrams, flowcharts, and validation data

9.4 General QA/QC

9.4.1 Correctness and Reliability

Many factors determine the correctness and reliability of the tests and/or the calibrations performed by a laboratory including:

- a) Human Factors
- b) Accommodation and Environmental Conditions
- c) Equipment
- d) Measurement Traceability
- e) Sampling
- f) Handling of test and calibration items

If GCT has not verified calibration, sample analysis may not occur until the instrument or analytical system has been calibrated. GCT does not use data with unacceptable calibration verification.

9.4.2 Uncertainty of Measurement

The extent to which the factors contribute to the total uncertainty of measurement differs considerably between tests and calibrations. The GCT Laboratory should account for these factors in developing test and calibration methods and procedures, in the training and qualification of personnel, and in the selection and calibration of equipment.

GCT shall:

- a) Evaluate the measurement of uncertainty for all calibrations, including its own equipment.
- b) Evaluate the measurement of uncertainty when performing testing. GCT follows its testing SOP's to satisfy this condition.

9.5 Accommodation and environmental conditions

9.5.1 Laboratory

GCT's laboratory facilitates the correct performance of the tests and/or calibrations, is suitable for GCT's laboratory activities, and does not adversely affect the validity of the results.

9.5.2 Monitor Environmental Conditions

GCT monitors and documents the environmental conditions of its laboratory to ensure correctness and reliability of the tests and/or calibrations.

9.5.3 Effective Separation

GCT has laboratory counter space to ensure there is an effective separation between areas where there are incompatible activities.

9.5.4 Control of Access

GCT controls the access to its laboratory. GCT shall cooperate with clients or their representatives in clarifying the client's request and in monitoring its laboratory's performance in relation to the work performed. Such cooperation may include:

- a) Clients or their representatives may monitor the test site or laboratories activities if and only if GCT can maintain the confidentiality of other clients.
- b) Preparation, packaging, and dispatch of items needed by the client for verification purposes.

9.5.5 Housekeeping

GCT takes measures to ensure its laboratory is kept clean of any conditions which would affect the outcome of tests and/or calibration results.

9.5.6 Laboratory Activities Outside the GCT Laboratory

When the GCT performs laboratory activities at sites or facilities outside its permanent control, the GCT Laboratory Manager shall ensure that the requirements related to facilities and environmental conditions of this document are met.

9.6 Test and Calibration Methods and Method Validation

9.6.1 General

GCT uses appropriate methods and procedures for all tests or calibrations within its scope, has instructions on the use of its equipment, and all manuals, standards, and reference data are kept up to date.

9.6.2 Method Selection

GCT uses test methods which comply with the Standards and meet the needs of the client. If the client does not specify a specific method, GCT shall select the appropriate method for the specific need of the client. Such method shall have been published in national or regional standards, or by reputable technical organizations. GCT shall use the latest valid edition of a standard.

9.6.3 Laboratory Developed Methods

GCT does not use laboratory developed methods.

9.6.4 Non-Standard Methods

GCT does not use non-standard methods.

9.6.5 Validation of Methods

GCT does not use non-standard methods, non-standard laboratory methods, or methods outside GCT's scope; therefore, validation of methods is not applicable in GCT's certification process or laboratory.

9.6.6 Estimation of Uncertainty

GCT uses an MDL procedure and calculation to estimate the uncertainty of its results. GCT uses 40 CFR 136 Appendix B, Method Detection Limit Revision 2. The Method Detection Limit is defined in GCT's SOP's.

9.6.7 Control of Data

Routine methods are documented in GCT's SOP's. SOP's are reviewed periodically and revised as needed. The references used for each method are documented in the SOPs.

- a) The GCT Laboratory uses appropriate methods and procedures for all tests within its scope. These include handling, storage, and preparation of samples to be evaluated.
- b) The GCT Laboratory has instructions on the use and operation of all relevant equipment, and on the handling and preparation of samples, where the absence of such instructions could jeopardize the results of tests.
- c) GCT's Laboratory uses test methods which meet the needs of the client and which are appropriate for the tests it undertakes.
- d) Calculations and data transfers are subject to appropriate checks in a systematic manner. Procedures are established and implemented for protecting the data.
- e) GCT uses spreadsheets designed by GCT personnel to record and report test data.
- f) Computer software used by GCT is documented in detail. The software is stored on GCT's cloud to protect the confidentiality of the client.
- g) Computers and automated equipment are maintained to ensure proper functioning and provided with the environmental and operating conditions necessary to maintain the integrity of test and calibration data.

9.6.8 Data Integrity System

GCT maintains a data integrity system and has a Quality Procedure for Data Integrity. There are four components to GCT's data integrity system.

9.6.8.1 Data Integrity Training

The GCT QA/QC officer shall conduct an annual data integrity training class with mandatory attendance by all GCT laboratory employees.

9.6.8.2 Data Integrity Documentation

All GCT employees shall sign an [Ethics Data Integrity Statement](#) which shall be kept on file pursuant to GCT's Document Control and Retention Policy.

9.6.8.3 Periodic Monitoring of Data Integrity

Data integrity involves reviewing documentation for errors and mistakes. The QA/QC Manager will randomly audit data pursuant to the Data Integrity Procedure.

9.6.8.4 Documentation of Data Integrity

All data integrity incidents must be documented pursuant to the Data Integrity Procedure.

9.7 Equipment

9.7.1 Sufficiency of Equipment

GCT has access to equipment (including, but not limited to, measuring instruments, software, measurement standards, reference materials, reference data, reagents, consumables, or auxiliary apparatus) that is required for the correct performance of laboratory activities and that can influence the results. If GCT lacks a specific piece of equipment for a test, GCT outsources the test.

9.7.2 Rented or Leased Equipment

When GCT uses equipment outside its permanent control, it shall ensure that the requirements for equipment in this Quality Manual are met.

9.7.3 Accuracy

GCT's equipment can achieve the accuracy required for the tests within GCT's scope of services. All equipment is calibrated pursuant to the Calibration Procedure prior to being put into service and then calibrated annually.

9.7.4 Authorized Personnel

GCT has trained personnel authorized to use its equipment. GCT maintains training logs of its trained personnel.

9.7.5 Identification of Equipment

GCT identifies all its equipment for testing and/or calibration in the SOP for the test. All equipment is calibrated prior to use.

9.7.6 Maintenance of Records

GCT maintains the following records on all its equipment:

- a) Identity of the item of equipment, including software and firmware version
- b) Manufacturer's name, type identification, and serial number
- c) Compliance of equipment with test and/or calibration
- d) Current location, where appropriate
- e) Calibration Dates, results of Calibrations, adjustments, repairs, acceptance criteria, and next scheduled calibration
- f) Documentation of reference materials, results, acceptance criteria, relevant dates, and the period of validity
- g) Manuals
- h) Maintenance Plan
- i) Damage and/or malfunction records

9.7.7 Maintenance

GCT ensures the equipment is maintained properly by documenting the maintenance in equipment logs.

9.7.8 Taking Equipment out of Service

Equipment that has been misused, overloaded, or is giving suspect results, shall be taken out of service. This equipment shall be marked as out of service until it has been repaired and shown by calibration or test to perform correctly. GCT shall examine the effect of the defective equipment on previous tests. If shown to have affected the tests, GCT shall institute Section 7.4.10, Control of Nonconforming Laboratory Testing.

9.7.9 Returning Equipment to Service

GCT shall verify that equipment conforms to specified requirements before being placed or returned into service.

9.7.10 Calibration

GCT calibrates equipment when:

- a) the measurement accuracy or measurement uncertainty affects the validity of the reported results, and/or
- b) calibration of the equipment is required to establish the metrological traceability of the reported results.

GCT has an SOP for calibration which is reviewed annually and adjusted as necessary. GCT has calibration stickers on the outside of all instruments requiring special calibration, including the date of the last calibration and the expiration date.

9.7.11 Equipment Removed Outside GCT's Laboratory

In the event equipment is removed from the GCT laboratory, GCT shall determine the equipment is in working order prior to placing the equipment back in service.

9.7.12 Intermediate Calibration

GCT has a procedure for all calibration requirements in every SOP. When intermediate checks are necessary to maintain confidence in the performance of the equipment, GCT does the checks pursuant to the SOP.

9.7.13 Correction Factors

If calibrations give rise to a correction factor, GCT shall ensure the correction factors are used in the final result.

9.7.14 Safeguarding Equipment

GCT's equipment is safeguarded by location and control of access.

9.7.15 Support Equipment

Support equipment, including ovens, balances, refrigerators, freezers, incubators, thermometers, and automatic dispensing devices, shall:

- a) Be maintained in proper working order
- b) Calibrated or verified at least annually; volumetric or dispensing devices shall be checked or verified quarterly
- c) Have data records retained to document equipment performance including maintenance activities and service calls
- d) Calibrated and or checked on the day the equipment is in use
- e) Volumetric dispensing devices shall be checked for accuracy on a quarterly basis (except Class A glassware and Glass microliter syringes)

9.8 Externally provided products and services

9.8.1 General

GCT's Laboratory shall ensure that only suitable externally provided products and services that affect laboratory activities are used, when such products and services:

- a) are intended for incorporation into the laboratory's own activities.
- b) are provided, in part or in full, directly to the client by the laboratory, as received from the external provider.
- c) are used to support the operation of the laboratory.

9.8.2 SOP's and Procedures

GCT has an SOP for acquiring externally provided products and services and retains all the records for:

- a) defining, reviewing, and approving the laboratory's requirements for externally provided products and services.
- b) defining the criteria for evaluation, selection, monitoring of performance and re-evaluation of the external providers.
- c) ensuring that externally provided products and services conform to the laboratory's established requirements, or when applicable, to the relevant requirements of this document before they are used or directly provided to the client.
- d) taking any actions arising from evaluations, monitoring of performance and re-evaluations of the external providers.

9.8.3 Communicating to external providers

GCT shall communicate its requirements to external providers for:

- a) The products and services to be provided
- b) The acceptance criteria
- c) Competence, including any required qualification of personnel.
- d) Activities that the laboratory, or its client, intends to perform at the external provider's premises.

9.9 Metrological Traceability

9.9.1 General

GCT, through SOP's and calibrations, establishes and maintains metrological traceability of its measurement results by means of a documented unbroken chain of calibrations, each contributing to the measurement uncertainty, linking them to an appropriate reference. GCT has a calibration procedure for all equipment and processes.

9.9.2 Traceability

GCT ensures that measurement results are traceable to the International System of Units (SI) through:

- a) calibration provided by a competent laboratory; or
- b) certified values of certified reference materials provided by a competent producer with stated metrological traceability to the SI; or
- c) direct realization of the SI units ensured by comparison, directly or indirectly, with national or international standards.

9.9.2.1 Calibration Laboratories

GCT is not a calibration laboratory.

9.9.2.2 Testing

GCT calibrates all measuring and testing equipment pursuant to its Calibration Procedure to ensure its laboratory can provide the uncertainty of measurement if necessary.

9.9.3 Reference Standards and Reference Materials

GCT has a procedure for the use of Reference Materials and Standards.

9.9.3.1 Reference Standards

GCT uses an outside calibration laboratory for its reference standards. GCT only uses the reference standards for calibration and no other purposes.

9.9.3.2 Reference Materials

In the event GCT uses reference materials, GCT will ensure they are traceable to SI units of measurement.

9.9.3.3 Reference Materials to Non-SI Units

When metrological traceability to the SI units is not technically possible, GCT shall demonstrate metrological traceability to an appropriate reference:

- a) certified values of certified reference materials provided by a competent producer.
- b) The results of reference measurement procedures, specified methods, or consensus standards that are clearly described and accepted as providing measurement results fit for their intended use and ensured by suitable comparison.

9.9.3.4 Transport and Storage

GCT maintains strict control of its reference standards and materials when transporting and follows the SOP's and manuals for the storage of reference standards and materials.

9.9.4 Additional Requirements

9.9.4.1 Correlation of Results

GCT shall provide satisfactory evidence of correlation of results by its participation in proficiency testing. The purpose of the TNI PT program is to provide a means for GCT to evaluate its laboratory's performance, under specified conditions relative to a given set of criteria in a specific area of testing, through analysis of proficiency testing (PT) samples provided by an external source.

To maintain accreditation, GCT shall analyze at least two TNI-compliant PT samples per calendar year for each accreditation for which its laboratory is accredited. The analysis dates of successive PT samples for the same accreditation shall be at least five (5) months apart and no longer than seven (7) months apart unless the PT sample is being used for corrective action to reestablish successful history to maintain continued accreditation. GCT shall maintain a history of at least two (2) successful performances out of the most recent three (3) attempts.

9.9.4.2 Documentation and Labeling

All standards, reagents, and reference materials shall be labeled and documented pursuant to GCT's SOP02 - Daily Laboratory Procedures. GCT shall analyze PT samples in the same manner as used for routine environmental samples using the same staff, sample tracking, sample preparation and analysis methods, standard operating procedures, calibration techniques, quality control procedures and acceptance criteria.

GCT shall retain all records necessary to facilitate historical reconstruction of the analysis and reporting of analytical results for PT samples for a minimum of five years. The historical records shall include a copy of the reporting forms used by GCT to report the analytical results for PT samples to the PTP. If the analytical results for the PT samples were entered or uploaded electronically to a PTP website, GCT shall retain a copy of the on-line data entry summary or similar documentation of entry of the PT results from the PTP's website.

9.10 Sampling

GCT has a sampling SOP for all its tests as well as SOP02 - Sample Receiving and Processing Procedure. Sampling pursuant to its certification activities is governed by the Standard to which GCT is certification. Sampling outside of GCT's certification activities is by client request. GCT does not sample or test for evidentiary or legal purposes.

9.10.1 GCT's Sampling SOP

GCT's sampling SOP includes:

- a) The selection of samples or sample sites.
- b) The sampling plan(s).
- c) The preparation and treatment of samples to yield the required item for subsequent testing.

9.10.2 Sample Documentation Requirements

GCT ensures the validity of the data by:

- a) Reference to the sampling method used.
- b) Having a documented system for uniquely identifying the samples to be tested, including date and time of sampling.
- c) Having a laboratory code that maintains an unequivocal link with the unique field ID code assigned to each sample.

- d) Identification of the GCT personnel performing the sampling.
- e) Identification of the equipment used.
- f) Environmental or transport conditions.
- g) Having the laboratory code durably marked on the sample container.
- h) Having the laboratory ID code entered into the laboratory records.
- i) Diagrams or other equivalent means to identify the sampling location, when appropriate.
- j) Deviations, additions to or exclusions from the sampling method and sampling plan.

9.10.3 Sample Acceptance Requirements

GCT has a written sample acceptance policy which includes the following:

- a) Proper, full, and complete documentation which includes sample identification, location, date and time of collection, collectors name, preservation type (if applicable), sample type, and special remarks
- b) Durable labels on the samples and indelible ink
- c) Use of appropriate sample containers
- d) Adherence to holding times
- e) Sufficient sample volume to perform the necessary tests
- f) Procedures to be used in the event the sample containers show signs of damage or contamination
- g) Qualification of data that does not meet the above requirements
- h) Client deviation of GCT's documented sampling procedure

9.10.4 Sample Receipt Protocols

GCT's SOP02 – Sample Receiving and Processing specifies the procedures for verifying and documenting sample preservation and procedures for samples not meeting acceptance criteria. If the sample does not meet the criteria, GCT shall either:

- a) Retain records regarding the final disposition of the sample
- b) Document any decision to proceed with the sample analysis
 - 1) Note the condition of the sample on the chain of custody
 - 2) Qualify the analysis of the data in the final report

9.10.4.1 Sample Logbook

GCT utilizes a permanent chronological record to document receipt of all samples.

- a) The record records the following:
 - 1) Client/Project Name
 - 2) Date and Time of Laboratory Receipt

- 3) Unique Laboratory ID code
- 4) Signature or initials of GCT Laboratory Personnel

b) GCT links the following information to the log record:

- 1) The field ID code, which identifies each sample, shall be linked to the laboratory ID code
- 2) The date and time of sample collection shall be linked to the sample and to the date and time of receipt in the laboratory
- 3) The requested analysis shall be linked to the laboratory ID code
- 4) Any comments resulting from inspection for sample rejection shall be linked to the laboratory ID code

9.10.4.2 Document Control

All documentation shall be retained pursuant to GCT's Document Control and Retention Policy. A complete chain of custody form shall be maintained for all samples received outside the test site.

If the client specifies the sample shall be used for evidentiary purposes, GCT shall utilize its sample acceptance SOP for legal chains of custody.

9.10.5 Sample Storage and Disposal

GCT shall store samples according to the preservation protocols in the GCT Laboratory Quality Manual as follows:

- a) Samples that require storage under refrigeration shall be with $\pm 2^{\circ}\text{C}$ of the recommended storage temperature.
- b) Samples shall be stored away from reagents, standards, and food and stored in such a manner as to prevent cross contamination.
- c) Sample disposal shall follow the appropriate disposal method in the SOP.

9.11 Handling of Test Items

GCT's SOP's include:

- a) A procedure for the transportation, receipt, handling, protection, storage, retention, and disposal of sample items
- b) A unique system for the unambiguous identification of sample items as specified in 9.8.2 of this Quality Manual

- c) A procedure for noting and recording deviations from specified conditions and putting a disclaimer in the report indicating which results may be affected by the deviation.
- d) A procedure to ensure the environmental conditions for samples under storage are maintained, monitored, and recorded.

9.12 Ensuring the Validity of Results

GCT SOP's ensures the validity of results. GCT's data is recorded so that trends are detectable, and where practicable, statistical techniques applied to review the results. GCT's monitoring includes:

- a) use of reference materials or quality control materials.
- b) functional check(s) of measuring and testing equipment.
- c) use of check or working standards with control charts, where applicable.
- d) intermediate checks on measuring equipment.
- e) correlation of results for different characteristics of an item.
- f) review of reported results.
- g) intralaboratory comparisons.
- h) testing of blind samples.

9.12.1 Performance Monitoring

GCT monitors its performance by participating in proficiency testing and through a Demonstration of Capability. GCT participates in proficiency testing twice per year for each accredited method and prior to using any method. New personnel are required to pass a proficiency test prior to performing a method. Additionally, GCT lab personnel will perform a proficiency test prior to using a new method or anytime a method has not been performed by GCT's laboratory or laboratory analyst in a twelve (12) month period.

9.12.2 Improving Performance

GCT uses data from monitoring activities to control and improve the laboratories activities. When results are found to be outside pre-defined limits, GCT takes appropriate action to prevent incorrect results from being reported.

9.13 Reporting

9.13.1 General

9.13.1.1 Review

The results of any test report shall be reviewed and authorized prior to release.

9.13.1.2 Results

GCT reports pursuant to the Standards to clients and regulatory agencies. Each report is customized for the specific needs of the clients or regulatory agencies. GCT retains all reports pursuant to its document control policy.

9.13.1.3 Additional Information

Any information not reported to the client in the test report shall be readily available to the client upon request.

9.13.2 Test Reports

GCT shall include the following information on all reports:

- a) Title
- b) Name and Address of its Laboratory
- c) Location of testing if not done at its laboratory
- d) Unique Identification of Test Report
- e) Name and Address of the client
- f) Identification of the Method Used
- g) Description and condition of the analyzed samples
- h) Date of the receipt of the analyzed item and sampling date
- i) Date of its laboratory evaluation
- j) Issue date of the report
- k) Sampling Plan and Procedures
- l) Details of environmental conditions
- m) A statement that the results only relate to the samples analyzed
- n) Test Results with units
- o) If applicable, additions to, deviations, or exclusion from the method
- p) Identification of the GCT personnel involved in creating the report
- q) Identification of results provided by external providers
- r) A statement specifying the report can only be reproduced in full with approval of GCT

GCT is responsible for all the information provided in the test report except for information provided by the client. Information provided by the client shall be noted in the test report. When GCT is not responsible for sampling, the test report shall state the results apply to the sample as received.

9.13.3 Specific Requirement for Test Reports

In addition to the requirements of 9.11.2 of this Quality Manual, test reports shall, where necessary for the interpretation of the test results, include the following information:

- a) information on specific test conditions, such as environmental conditions.
- b) where relevant, a statement of conformity with requirements or specifications.
- c) where applicable, the measurement uncertainty presented in the same unit as that of the measurand or in a term relative to the measurand (e.g., percent) when:
 - 1) It is relevant to the validity or application of the test results.
 - 2) A client requires the information.
 - 3) The measurement uncertainty affects conformity to a specification limit.
 - 4) Opinions and interpretations required by the client.
 - 5) Any additional information that may be required by specific methods, authorities, or clients.

When GCT is responsible for sampling, the samples shall meet the requirements of 9.10 of this Quality Manual.

9.13.4 Requirements for Calibration Certificates

GCT does not issue calibration certificates.

9.13.5 Opinions and interpretations

In the event GCT issues opinions and interpretations, they will be clearly identified and documented in the test report. Only the GCT employees authorized for the expression of opinions and interpretations release the respective statement. The opinions and interpretations expressed in the reports shall be based on the results obtained from the tested sample and clearly identified as such. If the opinions and interpretations are orally communicated to the client, a record of the dialogue shall be made and retained.

9.13.6 Reporting Statements of Conformity

When GCT reports to Standards, GCT shall document the decision rule employed, considering the level of risk associated with the decision rule employed, and apply the decision rule.

GCT reports on the statement of conformity so that the statement clearly identifies:

- a) To which results the statement of conformity applies.
- b) Specifications that are not met.
- c) The decision rule applied.

9.13.7 Testing and Calibration Results from Subcontractors

In the event GCT used subcontractors for testing, the results from the subcontractors shall be identified. GCT shall communicate the decision in writing to the client prior to using subcontractor and receive permission in writing from the contractor. However, permission in writing from the client is not required. In the event a client requests to have an analysis subcontracted, GCT will comply with the client's request. GCT shall only use accredited laboratories when subcontracting analyses. If GCT uses a subcontractor at its request, GCT will be responsible for the results; however, if the client requests a subcontractor, GCT is not responsible for the results. GCT has a list of approved subcontractors.

9.13.8 Electronic Transmission of Results

All requirements of the Quality Manual shall be met regardless of how the report is transmitted.

9.13.9 Formatting of Reports

GCT formats reports to accommodate the client or regulatory agency for which the data was collected.

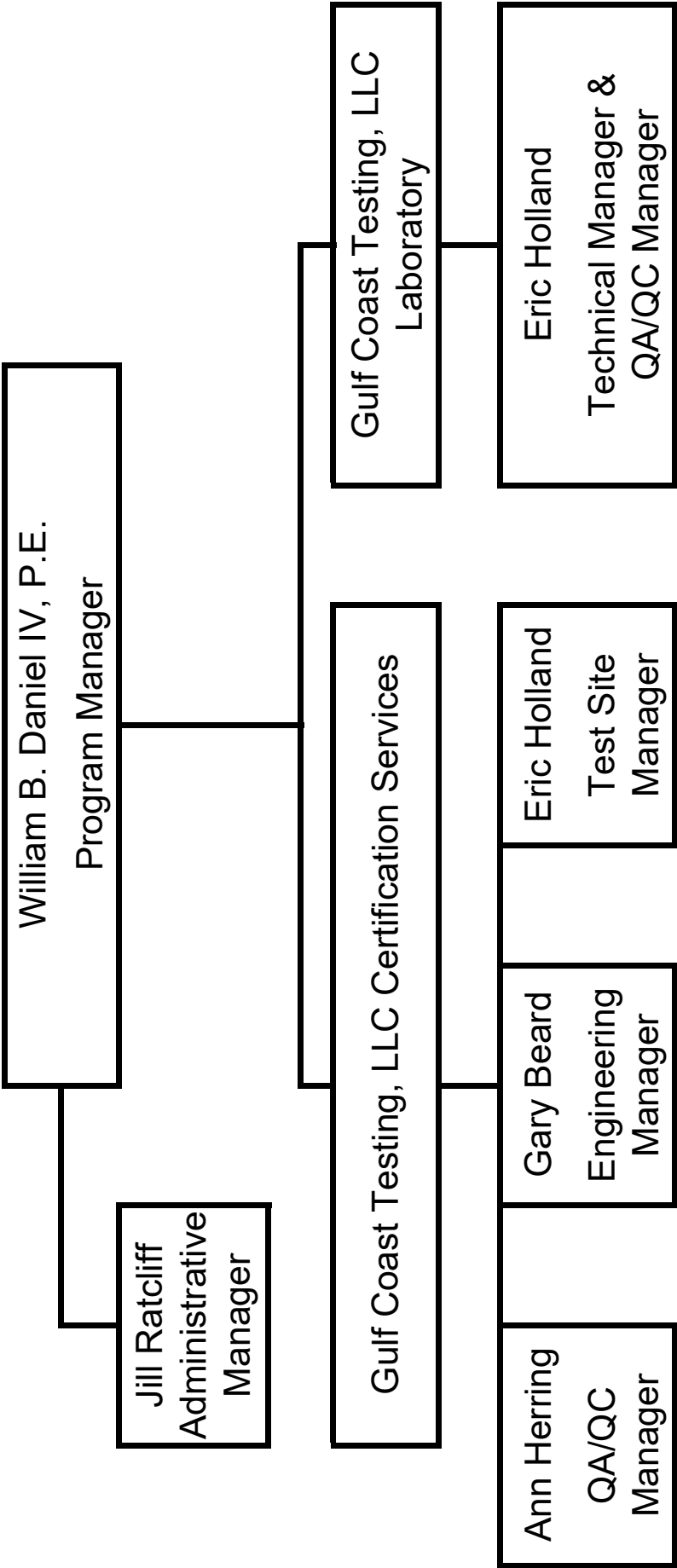
9.13.10 Amendments to Test Reports

Material amendments to the test report shall meet all the requirements of the ISO/IEC 17065 and ISO/17025 and be made as follows:

- a) In the form of a further document.
- b) The reason for the change shall be included in the report.
- c) When is it necessary to issue a complete new report, the report shall be uniquely identified.

ANNEX A – ORGANIZATION CHART

Gulf Coast Testing, LLC Organization Chart



ANNEX B – Job Qualifications

Annex B

Job Descriptions and Qualifications

Program Manager

Job Description:

Responsible for:

1. All aspects of GCT's Quality Management System.
2. All aspects of GCT's operations including but not limited to:
 - a. Decisions on certification including new products and the approval/denial of request for engineering services such as evaluation of alternative materials, components and scale-up of certified wastewater treatment systems.
 - b. Sub-contractor selection.
 - c. Submittal of clients' requests to subcontractor.
 - d. Supervision of the implementation of the program's policies through management reviews.
 - e. Resolution of complaints.
 - f. Planning and coordination of evaluations and task activities on a project basis and serving as project manager on each; responsible for client interface, budget/schedule tracking, and invoicing.
 - g. Formulation of policy matters relating to the operation of the certification body including the updating of the ANSI Certification Program Manual. Responsible for monitoring for ANSI's periodic updates to the requirements for accreditation and incorporating these requirements into the Program Manual.
3. Supervision of the finances.
4. Activities of all employees.

Minimum Job Qualifications:

Engineering Degree and/or Master's Degree in Business Administration
10 years working experience, preferably in engineering with Professional Engineer Certification
10 years management experience

Annex B

Job Descriptions and Qualifications

Deputy Manager or QA/QC Officer (Certification)

Job Description:

Responsible for:

1. All activities of the Program Manager in his/her absence
2. Communication with manufacturers with respect to written requests for the engineering services such as evaluation of alternative materials, components and scale-up of certified systems and assist in performance of annual audits of the manufacturers and their distributors.
3. Gather information for submittal of client's request to subcontractor.
4. Implements Quality Assurance Programs
5. Communication with manufacturers with respect to written requests for submittal of Standard Performance Evaluations to state agencies.
6. Maintenance of Confidential files.
7. Distribution of the ANSI Certification Program Manual.
8. Administration of the annual ANSI audit - accompany ANSI auditor during audit and respond to audit report.
9. Health and safety manager for the lab.
10. Appoint lead auditor for annual internal audit.
11. Submit a report of the findings from the audit.
12. Verify that corrective actions are implemented.

Minimum Qualifications:

Bachelor of Science in Science or Administrative Related Field
10 years working experience in Environmental Management

Annex B

Job Descriptions and Qualifications Laboratory Technical Manager and QA/QC Manager

Job Description:

Responsible for:

1. Serves as the technical resource for the laboratory
2. Writes all the laboratory SOP's and Laboratory Handbook
3. Health and safety manager for the lab.
4. Responsible for lab accreditation process
5. Verify that laboratory corrective actions are implemented.

Minimum Qualifications:

Bachelor degree in Chemistry, Environmental Science, Biological Science,
Physical Science, or Engineering

24 hours in Chemistry with 4 of the hours in Microbiology

2 years of laboratory experience (Masters or Doctorate may substitute for 1 year of experience)

See Following page for Specific Qualifications for Laboratory Type

Annex B

TECHNICAL DIRECTOR QUALIFICATIONS BY LABORATORY TYPE

Technical Director of Chemistry Lab

24 hours in Chemistry

2 years of experience; Masters or Doctorate may substitute for 1 year of experience (see disciplines below)

Bachelor's degree in Chemical, Environmental, Biological Sciences, Physical Sciences, or Engineering

Technical Director of Inorganic Chemistry Lab (no metals)

16 hours in Chemistry

2 years of experience

Associate degree in Chemical, Physical or Environmental Sciences

Technical Director of Microbiology or Biology Lab

16 hours in Microbiology and Biology

2 years of experience; Masters or Doctorate may substitute for 1 year of experience (see disciplines below)

Bachelor's Degree in Microbiology, biology, Chemistry, Environmental Sciences, Physical Sciences or Engineering

Technical Director of Microbiology Lab performing only fecal coli form, total coli form or standard plate counts

4 hours in Microbiology

1 year of experience

Associate Degree in Science or Applied Science, or two years of college education may substitute for the Associate Degree

Technical Director of Radiochemistry Lab

24 hours in Chemistry

2 years of experience in radiochemistry

Bachelor's Degree in Chemistry, Physics or Engineering; Master or Doctorate; may substitute for 1 year of experience

Annex B

Job Descriptions and Qualifications

Engineering Manager

Job Description:

Responsible for:

1. Performing engineering work in regard to the design and operation of certified treatment systems.
2. Investigating and inspecting through site visits the quality of the operations and activities carried out by the Laboratory and Field Technical Manager to ensure compliance with approved codes of practice and standards.
3. Keeping abreast with the latest requirements of ANSI/NSF Standards.

Minimum Qualifications:

Bachelor's degree in Engineering

Professional Engineer Certification

10 years working experience in design and maintenance of wastewater treatment systems

Annex B

Job Descriptions and Qualifications

Laboratory and Field Technician

Job Description:

Responsible for:

1. Maintaining the laboratory facilities.
2. Insuring all testing and insures proper procedures are followed.
3. Working with Laboratory Technical Manager to implement Vendor List.
4. Implementing quality assurance programs.
5. Maintaining a variety of records and reports in manual and computerized format relative to lab results, calibration results, entry/exit logs, repairs, etc.
6. Requisitioning laboratory supplies

Minimum Qualifications:

High School Graduate

Five years working experience

Knowledge of Calibration Requirements and Reference Standards

Annex C – Method Accreditation and Number

Annex C

METHOD ACCREDITATION AND NUMBER

<u>Method</u>	<u>Accreditation</u>	<u>Method Number</u>
BOD ₅ /CBOD ₅	Standard Methods	5210B
TSS	Standard Methods	2540D
pH	EPA	9040C

ANNEX D – Nominal Cross-Reference ISO 17065, ISO 17025, ISO 17020, and TNI Standard

ANNEX A
Nominal Cross -References to ISO 17065:2012, ISO 17025:2017, 17020:2012, and TNI:2016

GCT Quality Manual Title	ISO 17065	ISO 17025	ISO 17020	TNI Standard
1.0 Scope	Par. 1.0	Par. 1.0	Par. 1.0	1.0
2.0 Normative References	2.0	2.0	2.0	2.0
3.0 Terms and Definitions	3.0	3.0	3.0	3.0
3.1. Client	3.1	NA	NA	NA
3.2. Consultancy	3.2	NA	NA	NA
3.3. Evaluation	3.3	NA	NA	NA
3.4. Product	3.3	NA	NA	NA
3.5. Process	3.4	NA	NA	NA
3.6. Service	3.5	NA	NA	NA
3.7. Certification Requirements	3.6	NA	NA	NA
3.8. Product Requirement	3.7	NA	NA	NA
3.9. Certification Scheme	3.8	NA	NA	NA
3.10. Scopes of Certification	3.9	NA	NA	NA
3.11. Scheme Owner	3.10	NA	NA	NA
3.12. Certification Body	3.11	NA	NA	NA
3.13. Impartiality	3.12	3.1	NA	NA
3.14. Standard	3.13	NA	NA	NA
3.15. Supplier	NA	NA	NA	NA
3.16. Test	NA	NA	NA	NA
3.17. Conformity	NA	NA	NA	NA
3.18. Nonconformity	NA	NA	NA	NA
3.19. Quality Manual	NA	NA	NA	NA
3.20. Laboratory Technical Manager	NA	NA	NA	NA
3.21. QA/QC Officer (Certification)	NA	NA	NA	NA
3.22. QA/QC Officer (Laboratory)	NA	NA	NA	NA
3.23. Laboratory	NA	3.6	NA	NA
3.24. Off-Site Testing	NA	NA	NA	NA
3.25. Qualified Personnel	NA	NA	NA	NA
3.26. Model	NA	NA	NA	NA
3.27. Accreditation Body	NA	NA	NA	NA
3.28. Acceptance Criteria	3.1	NA	NA	NA
3.29. Accuracy	3.2	NA	NA	NA
3.30. Analytical Uncertainty	3.3	NA	NA	NA
3.31. Batch	3.3	NA	NA	NA
3.32. Analytical batch	3.4	NA	NA	NA
3.33. Bias	3.5	NA	NA	NA
3.34. Blank	3.6	NA	NA	NA
3.35. Calibration	3.7	NA	NA	NA
3.36. Calibration Curve	3.8	NA	NA	NA
3.37. Calibration Standard	3.9	NA	NA	NA
3.38. Chain of Custody	3.10	NA	NA	NA
3.39. Demonstration of Capability	3.11	NA	NA	NA
3.40. Field of Accreditation	3.12	NA	NA	NA
3.41. Finding	3.13	NA	NA	NA
3.42. Laboratory Control Sample	NA	NA	NA	NA
3.43. Legal Chain of Custody Protocols	NA	NA	NA	NA
3.44. Limit(s) of Detections (LOD)	NA	NA	NA	NA
3.45. Limit(s) of Quantification (LOQ)	NA	NA	NA	NA

ANNEX A
Nominal Cross -References to ISO 17065:2012, ISO 17025:2017, 17020:2012, and TNI:2016

GCT Quality Manual Title	ISO 17065	ISO 17025	ISO 17020	TNI Standard
3.46. Matrix	NA	NA	NA	NA
3.47. Matrix Duplicate	NA	NA	NA	NA
3.48. Matrix Spike	NA	NA	NA	NA
3.49. Matrix Spike Duplicate	NA	NA	NA	NA
3.50. Measurement System	NA	NA	NA	NA
3.51. Method	NA	NA	NA	NA
3.52. Mobile Laboratory	NA	NA	NA	NA
3.53. Precision	NA	NA	NA	NA
3.54. Preservation	NA	NA	NA	NA
3.55. Procedure	3.1	NA	NA	NA
3.56. Proficiency Testing	3.2	3.5	NA	NA
3.57. Proficiency Testing Program	3.3	NA	NA	NA
3.58. Proficiency Testing Sample	3.3	NA	NA	NA
3.59. Protocol	3.4	NA	NA	NA
3.60. Quality Assurance	3.5	NA	NA	NA
3.61. Quality Control	3.6	NA	NA	NA
3.62. Quality Control Sample	3.7	NA	NA	NA
3.63. Raw Data	3.8	NA	NA	NA
3.64. Reference Material	3.9	NA	NA	NA
3.65. Reference Standard	3.10	NA	NA	NA
3.66. Reference Method	3.11	NA	NA	NA
3.67. Sampling	3.12	NA	NA	NA
3.68. Complaint	3.13	3.2	NA	NA
3.69. Interlaboratory Comparison	NA	3.3	NA	NA
3.70. Intralaboratory Comparison	NA	3.4	NA	NA
3.71. Decision Rule	NA	3.7	NA	NA
3.72. Validation	NA	3.9	NA	NA
3.73. Standard Operating Procedure (SOP)	NA	NA	NA	NA
3.74. Traceability	NA	NA	NA	NA
3.75. Verification	NA	3.8	NA	NA
4.0 General Requirements	4.0	4.0	4.0	4.0
4.1 Legal and Contractual Matters	4.1	NA	NA	4.1
4.1.1 Legal Responsibility	4.1.1	5.1, 5.5	NA	4.1.1
4.1.2 Certification Agreement	4.1.2	7.1.4, 7.1.5, 7.1.6	NA	NA
4.1.3 Use of License, Certification, and Marks of Conformity	4.1.3	NA	NA	NA
4.2 Management of Impartiality	4.2	4.1	NA	NA
4.2.1 Impartiality	4.2.1	4.1.1	4.1.1	4.1.4
4.2.2 Responsibility	4.2.2	4.1.3	4.1.2	NA
4.2.3 Risks to Impartiality	4.2.3	4.1.4	4.1.3	NA
4.2.4 Minimizing Risk to Impartiality	4.2.4	4.1.5, 5.2	4.1.4	NA
4.2.5 Impartiality of Management	4.2.5	4.1.2	4.1.5	4.15
4.2.6 GCT Consultants and Impartiality	4.2.6	4.1.5	4.1.6 a)	NA
4.2.7 Other Entities	4.2.7	NA	4.1.6 b)	4.1.4
4.2.8 Separate Legal Entities	4.2.8	NA	4.1.6 c)	4.1.4
4.2.9 Consultancy	4.2.9	NA	NA	NA

ANNEX A
Nominal Cross -References to ISO 17065:2012, ISO 17025:2017, 17020:2012, and TNI:2016

GCT Quality Manual Title	ISO 17065	ISO 17025	ISO 17020	TNI Standard
4.2.10 Prohibition of Consultancy	4.2.10	NA	NA	NA
4.2.11 Response to Risks of Impartiality	4.2.11	4.1.5	NA	NA
4.1.12 Actions of Employees and Consultants	4.1.12	NA	NA	NA
4.3 Liability and Financing	4.3	NA	NA	NA
4.3.1 Ownership	4.3.1	NA	NA	NA
4.3.2 Financial Resources	4.3.2	NA	NA	NA
4.4 Non-Discriminatory Conditions	4.4	NA	NA	NA
4.4.1 Policy	4.4.1	NA	NA	NA
4.4.2 Access to Certification	4.4.2	NA	NA	NA
4.4.3 Non-Conditional Access	4.4.3	NA	NA	NA
4.4.4 Scope of Certification	4.4.4	5.3	NA	NA
4.5 Confidentiality	4.5	4.2	4.2	NA
4.5.1 Confidential Information of Clients	4.5.1	4.2.1	4.2.1	4.7.1
4.5.2 Legal Documents	4.5.2	4.2.2	4.2.2	NA
4.5.3 Additional Client Information	4.5.3	4.2.3	4.2.3	NA
4.6 Publicly Available Information	4.6	7.5.2	7.5.2	NA
4.7 Procurement	4.7	NA	6.2.11	4.6
4.7.1 Procurement Policy	NA	NA	NA	4.6.1
4.7.2 Purchased Supplies	NA	NA	NA	4.6.2
4.7.3 Documents	NA	NA	NA	4.6.3
4.7.4 Critical Supplies	NA	NA	NA	4.6.4
4.8 Agreement with ANSI	NA	NA	NA	NA
5.0 Structural Requirements	5.0	NA	NA	4.1.5
5.1 Organization Structure and Top Management	5.1	5.2, 5.7(a), 5.7(b)	5.2.2	4.1.5
5.1.1 Certification and Impartiality	5.1.1	NA	5.2.1	4.1.5, 4.2.6
5.1.2 Organizational Structure	5.1.2	5.5(a)	5.1.1, 5.1.2, 5.2.3, 5.2.4, 5.2.7	4.1.5, 4.2.6
5.1.3 Organizational Responsibility	5.1.3	5.5(b), 5.5(c), 5.6(a), 5.6(b), 5.6(c), 5.6(d), 5.6(e), 6.2.6	5.1.3, 5.1.4, 5.1.5, 5.2.5, 5.2.6	4.1.5, 4.1.7
5.1.4 Committees	5.1.4	NA	NA	NA
5.2 Mechanism for Safeguarding Impartiality	5.2	NA	NA	NA
5.2.1 Mechanism	5.2.1	NA	5.2.1	NA
5.2.2 Documentation of Impartiality	5.2.2	NA	5.2.2	NA
5.2.3 Impartiality of Management	5.2.3	NA	NA	NA
5.2.4 Interested Parties	5.2.4	NA	NA	4.7.2
6.0 Resource Requirements	6.0	6.0	NA	NA
6.1 Certification Body and Laboratory Personnel	6.1	NA	NA	4.1.2, 4.1.5, 4.2.6, 5.2
6.1.1 General	6.1.1	6.1, 6.2.1, 6.2.2, 6.2.4	6.1.1, 6.1.2, 6.1.3, 6.1.4	4.7, 5.2.5, 5.2.6, 5.2.7
6.1.2 Management of Competence for GCT Certification Personnel	6.1.2	6.2.3, 6.2.5	6.1.5, 6.1.6, 6.1.7, 6.1.8, 6.1.9, 6.1.10	5.2.2, 5.2.4
6.1.3 Contract with the Personnel	6.1.3	NA	6.1.11, 6.1.12, 6.1.13	4.1.5, 5.2.3
6.2 Resources for Evaluation	6.2	NA	6.2	NA
6.2.1 Internal Resources	6.2.1	6.2.3	6.2.1, 6.2.2, 6.2.3, 6.2.4	4.1.2

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Nominal Cross -References to ISO 17065:2012, ISO 17025:2017, 17020:2012, and TNI:2016

GCT Quality Manual Title	ISO 17065	ISO 17025	ISO 17020	TNI Standard
	Par.	Par.	Par.	Par
6.2.2 External Resources	6.2.2	6.6	NA	4.4.3, 4.4.4, 4.5, 4.5.1, 4.5.2, 4.5.3, 4.5.4
7.0 Process Requirements	7.0	7.0	7.0	4.4
7.1 General	7.1	NA	7.1	NA
7.1.1 Certification Scheme	7.1.1	NA	7.1.1	NA
7.1.2 Certification Requirements	7.1.2	NA	7.1.2	NA
7.1.3 Certification Explanations	7.1.3	NA	7.1.3	NA
7.1.4 Laboratory Capabilities	NA	5.4, 7.1.1(a), (b), (c), (d), 7.1.2, 7.1.3	NA	4.4.1
7.2 Application	7.2	NA	NA	4.4, 4.4.1, 4.4.2
7.3 Application Review	7.3	NA	NA	4.4.2
7.3.1 Review of Application Information	7.3.1	NA	7.1.4, 7.1.5	4.7.1
7.3.2 Certification of Products with no prior experience	7.3.2	NA	NA	NA
7.3.3 Certification Justification of a Product	7.3.3	NA	NA	NA
7.3.4 Declining Certification of a Product	7.3.4	NA	NA	NA
7.3.5 Certification of Similar Products	7.3.5	NA	NA	NA
7.4 Evaluation	7.4	NA	NA	NA
7.4.1 Evaluation Plan	7.4.1	NA	NA	NA
7.4.2 Assignment of Personnel	7.4.2	NA	NA	NA
7.4.3 Documentation for Evaluation	7.4.3	NA	NA	NA
7.4.4 Evaluation Process	7.4.4	NA	7.1.6, 7.1.7, 7.1.9	NA
7.4.5 Evaluation Results	7.4.5	NA	7.1.8	NA
7.4.6 Evaluation Non-Conformities	7.4.6	NA	NA	NA
7.4.7 Evaluation Process with Non-Conformities	7.4.7	NA	NA	NA
7.4.8 Documentation of Evaluation Process with Non-Conformities	7.4.8	NA	NA	NA
7.4.9 Documentation of Evaluation Activities Prior to Review	7.4.9	NA	7.3.1, 7.3.2	NA
7.4.10 Control of Nonconforming Laboratory Testing	NA	7.10, 7.10.1, 7.10.2, 7.10.3	NA	4.9, 4.9.1, 4.9.2
7.5 Review	7.5	NA	NA	NA
7.5.1 Certification Review	7.5.1	NA	NA	NA
7.5.2 Documentation of Review	7.5.2	NA	7.4.1, 7.4.2, 7.4.3, 7.4.4, 7.4.5	NA
7.6 Certification Decision	7.6	NA	NA	NA
7.6.1 Responsibility for Certification	7.6.1	NA	NA	NA
7.6.2 Personnel Responsible for Certification	7.6.2	NA	NA	NA
7.6.3 Employment by GCT	7.6.3	NA	NA	NA
7.6.4 Organization Control	7.6.4	NA	NA	NA
7.6.5 Personnel with entities under Organizational Control	7.6.5	NA	NA	NA

ANNEX A
Nominal Cross -References to ISO 17065:2012, ISO 17025:2017, 17020:2012, and TNI:2016

GCT Quality Manual Title	ISO 17065		ISO 17025		ISO 17020		TNI Standard	
	Par.		Par.		Par.		Par	
7.6.6 Declining to grant certification	7.6.6		NA		NA		NA	
7.7 Certification Documentation	7.7		NA		NA		NA	
7.7.1 GCT's Certification Documents	7.7.1		NA		NA		NA	
7.7.2 Signing of Certification Documents	7.7.2		NA		NA		NA	
7.7.3 Timing of Release of Certification Documentation	7.7.3		NA		NA		NA	
7.8 Directory of Certified Products	7.8		NA		NA		NA	
7.9 Surveillance	7.9		NA		NA		NA	
7.9.1 Annual Compliance Audits	7.9.1		NA		NA		NA	
7.9.2 Evaluation, Review, and Certification	7.9.2		NA		NA		NA	
7.9.3 Compliance Audits and Certification	7.9.3		NA		NA		NA	
7.9.4 Annual Compliance Audits for Process or Service	7.9.4		NA		NA		NA	
7.10. Changes Affecting Certification	7.10		NA		NA		NA	
7.10.1 Changes in Standards	7.10.1		NA		NA		NA	
7.10.2 Changes by Client	7.10.2		NA		NA		NA	
7.10.3 Implementation of Changes affecting certification	7.10.3		NA		NA		NA	
7.11 Termination, reduction, suspension, or withdrawal of certification	7.11		NA		NA		NA	
7.11.1 Action on Nonconformance	7.11.1		NA		NA		NA	
7.11.2 Action on Nonconformance with Evaluation	7.11.2		NA		NA		NA	
7.11.3 Termination or Withdrawal of Certification	7.11.3		NA		NA		NA	
7.11.4 Suspension of Certification	7.11.4		NA		NA		NA	
7.11.5 Resolution of Suspension of Certification	7.11.5		NA		NA		NA	
7.11.6 Reinstatement of Suspended Certification	7.11.6		NA		NA		NA	
7.12 Records	7.12		NA		NA		4.3, 4.3.3, 4.13, 4.13.1	
7.12.1 Records Retention Policy	7.12.1		NA		NA		4.3, 4.13.1, 4.13.2	
7.12.2 Confidentiality of Records	7.12.2		NA		NA		4.1.5, 4.13.1	
7.12.3 Re-evaluation of Certification Records	7.12.3		NA		NA		NA	
7.12.4 Correcting Mistakes in Records	NA		NA		NA		4.13.2	
7.13 Complaints and Appeals	7.13		7.9		NA		4.8	
7.13.1 Complaint and Appeals Process	7.13.1		7.9.1, 7.9.2		7.5.1, 7.6.1		4.8	
7.13.2 Complaints and Appeals Applicability	7.13.2		7.9.3		7.5.3		4.8	
7.13.3 Formal and Informal Complaints and Appeals	7.13.3		7.9.3		NA		4.8	

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Nominal Cross -References to ISO 17065:2012, ISO 17025:2017, 17020:2012, and TNI:2016

GCT Quality Manual Title	ISO 17065	ISO 17025	ISO 17020	TNI Standard
	Par.	Par.	Par.	Par
7.13.4. Information for Complaints and Appeals	7.13.4	7.9.4, 7.9.5	7.6.2	4.8
7.13.5. Decisions on Complaints and Appeals	7.13.5	7.9.6	7.5.4	4.8
7.13.6. Conflicts of Interest	7.13.6	NA	7.13.4	4.8
7.13.7. Notice	7.13.7	NA	NA	4.8
7.13.8. Notification of Outcome	7.13.8	7.9.7	7.5.5, 7.6.3, 7.6.5	4.8
7.13.9. Resolution	7.13.9	NA	NA	4.8
8.0 Management System Requirements	8.0	8.0	NA	4.0
8.1. Options	8.1.	8.1.	NA	4.2.1
8.1.1. "Option A" CB	8.1.1.	8.1.1	8.1.1	4.2.1
8.1.2 Management System Information	8.1.2	8.1.2	8.1.2	4.2
8.1.3. ISO/IEC 9001	8.1.3.	8.1.3	8.1.3	1.0
8.2. General Management System Documentation	8.2.	5.6, 8.2	NA	4.2
8.2.1. Policies and Objectives	8.2.1.	5.7(a), 5.7(b), 8.2.1, 8.2.2, 8.5	8.2.1	4.2.1
8.2.2. Commitment to Management System	8.2.2.	5.6(a), 5.6(b), 5.6(c), 5.6(d), 5.6(e), 8.2.3	8.2.2	4.2.2, 4.2.3, 4.2.4, 4.10
8.2.3. Responsibility to Maintain Management System	8.2.3.	5.6, 8.2.5, 8.5.2, 8.5.3	8.2.3	4.2.1, 4.2.7
8.2.4. Documentation of Management System	8.2.4.	8.2.4	8.2.4	4.2.2, 4.2.5
8.2.5 Access to Documents	8.2.5	8.2.5	8.2.5	4.2.1
8.3. Control of Documents	8.3.	8.3.	8.3	4.3
8.3.1. Records Retention Procedure	8.3.1.	8.3.1.	8.3.1	4.3, 4.13
8.3.2. Records and Documents Policy	8.3.2.	8.3.2.	8.3.2	4.3, 4.13
8.4. Control of Records	8.4.	8.4.	8.4	4.3.1, 4.13
8.4.1. Records and Documents Control Policy	8.4.1.	8.4.1.	8.4.1	4.3.2, 4.13
8.4.2. Records and Documents Retention Policy	8.4.2.	8.4.2.	8.4.2	4.3.2, 4.13
8.4.3 Laboratory Technical Records Requirements	NA	7.5.1, 7.5.2, 7.11, 7.11.1, 7.11.2,	NA	4.13.2
8.4.4 Sample Collection Data Requirements	NA	7.1.8, 7.11.3, 7.11.4, 7.11.5, 7.11.6	NA	4.13.3
8.5. Management Review	8.5.	8.9	8.5	4.15, 4.16, 4.2.2
8.5.1. General	8.5.1.	8.9.1	8.5.1	14.5
8.5.2. Review of Inputs to Management Review	8.5.2.	8.9.2	8.5.2	4.1.6, 4.2.7
8.5.3. Review Outputs	8.5.3.	8.9.3	8.5.3	4.15.2
8.5.4 Data Integrity Investigations	NA	NA	NA	4.16
8.6. Internal Audits	8.6.	8.8	8.6	4.14
8.6.1. Internal Audit Procedure	8.6.1.	8.8.1	8.6.1	4.14.1
8.6.2. Audit Assurance Procedure	8.6.2.	8.8.2	8.6.2	4.14.3
8.6.3. Audit Frequency	8.6.3.	8.8.2	8.6.3, 8.6.4	4.14.1
8.6.4. Audit Requirements and Outcomes	8.6.4.	8.8.2	8.6.5	4.14.1, 4.14.2, 4.14.3, 4.14.4

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GCT Quality Manual Title	ISO 17065	ISO 17025	ISO 17020	TNI Standard
8.6.5 Notification of Clients	NA	8.8.2	8.6.5	14.14.5
8.7. Corrective Actions	8.7.	8.8.2	8.7.	8.7.
8.7.1. Corrective Actions	8.7.1.	8.7.1	8.7.1	4.11.1
8.7.2. Nonconformities	8.7.2.	8.7.1(a), 8.7.1(b), 8.7.1(c)	8.7.2	4.11.2
8.7.3. Appropriateness of Corrective Actions	8.7.3.	8.7.1(d), 8.7.1(e), 8.7.1(f)	8.7.3	4.11.3
8.7.4. Corrective Action Procedure Requirements	8.7.4.	8.7.1, 8.7.2, 8.7.3	8.7.4	4.11.4
8.7.5 Additional Audits	NA	NA	8.7.4	8.7.5
8.7.6 Documented Procedures	NA	NA	8.7.4	8.7.6
8.7.7 Systemic Error	NA	NA	8.7.4	8.7.7
8.8. Preventative Actions	8.8.	8.5	8.8	4.12
8.8.1. Preventative Actions	8.8.1.	8.5.1	8.8.1	4.12.1
8.8.2. Appropriateness of Preventative Actions	8.8.2.	8.5.3	8.8.2	4.12.1, 4.12.2
8.8.3. Preventative Action Procedure Requirements	8.8.3.	8.5.2	8.8.3	4.12.2
9.0 Technical and Management Requirements for GCT Laboratory	NA	NA	NA	5.0
9.1 Laboratory Quality Manual	NA	NA	NA	NA
9.1.1 Laboratory Quality Manual Reponsibility	NA	NA	NA	4.2.8.2
9.1.2 Laboratory Quality Manual Items	NA	NA	NA	4.2.8.3
9.1.3 Laboratory Quality Manual References	NA	NA	NA	4.2.8.4
9.2 GCT SOP's	NA	8.6, 8.6.1, 8.6.2, 5.5(c)	NA	4.2.8.5
9.3 Selection and Verification of Methods	NA	7.2	NA	NA
9.4 General QA/QC	NA	NA	NA	5.1
9.4.1 Correctness and Reliability	NA	NA	NA	5.1.1
9.4.2 Uncertainty of Measurement	NA	NA	NA	5.1.2
9.5 Accommodation and environmental conditions	NA	6.3	NA	4.1.3, 5.3
9.5.1 Laboratory	NA	6.3.1	NA	5.3.1
9.5.2 Monitor Environmental Conditions	NA	6.3.2, 6.3.3, 6.3.4	NA	5.3.2
9.5.3 Effective Separation	NA	NA	NA	5.3.3
9.5.4 Control of Access	NA	7.1.7	NA	5.3.4
9.5.5 Housekeeping	NA	NA	NA	5.3.5
9.6 Test and Calibration Methods and Method Validation	NA	NA	6.2.5, 6.2.6, 6.2.7, 6.2.8, 6.2.9, 6.2.10	5.4
9.6.1 General	NA	NA	NA	5.4.1
9.6.2 Method Selection	NA	6.2.6	NA	5.4.2
9.6.3 Laboratory Developed Methods	NA	NA	NA	5.4.3
9.6.4 Non-Standard Methods	NA	NA	NA	5.4.4
9.6.5 Validation of Methods	NA	7.2.2, 7.2.2.1, 7.2.2.3, 7.2.2.4	NA	5.4.5

ANNEX A
Nominal Cross -References to ISO 17065:2012, ISO 17025:2017, 17020:2012, and TNI:2016

GCT Quality Manual Title	ISO 17065		ISO 17025		ISO 17020		TNI Standard	
	Par.	Par.	Par.	Par.	Par.	Par.	Par.	Par.
9.6.6 Estimation of Uncertainty	NA	NA	NA	NA	NA	NA	5.4.6	5.4.6
9.6.7 Control of Data	NA	NA	NA	NA	NA	NA	5.4.7	5.4.7
9.6.8 Data Integrity	NA	NA	NA	NA	NA	NA	4.2.8.1	4.2.8.1
9.7 Equipment	NA	NA	NA	NA	NA	NA	5.5	5.5
9.7.1 Sufficiency of Equipment	NA	6.4.6	NA	NA	NA	NA	5.5.1	5.5.1
9.7.2 Rented or Leased Equipment	NA	6.4.2	NA	NA	NA	NA	5.4.2	5.4.2
9.7.3 Accuracy	NA	6.4.5	NA	NA	NA	NA	NA	NA
9.7.4 Authorized Personnel	NA	NA	NA	NA	NA	NA	5.5.3	5.5.3
9.7.5 Identification of Equipment	NA	NA	NA	NA	NA	NA	5.5.4	5.5.4
9.7.6 Maintenance of Records	NA	6.4.13	NA	6.2.15	NA	NA	5.5.5	5.5.5
9.7.7 Maintenance	NA	6.4.3, 6.4.13	NA	6.2.9	NA	NA	5.5.3	5.5.3
9.7.8 Taking equipment out of service	NA	6.4.3, 6.4.9	NA	6.2.14	NA	NA	5.5.7	5.5.7
9.7.9 Returning equipment to service	NA	6.4.4	NA	NA	NA	NA	NA	NA
9.7.10 Calibration	NA	6.4.6, 6.4.7, 6.4.8	NA	NA	NA	NA	5.5.8	5.5.8
9.7.11 Equipment Removed Outside of the Laboratory	NA	6.4.3	NA	NA	NA	NA	5.5.9	5.5.9
9.7.12 Intermediate Calibration	NA	6.4.10	NA	NA	NA	NA	5.5.10	5.5.10
9.7.13 Correction Factors	NA	6.4.11	NA	NA	NA	NA	5.5.11	5.5.11
9.7.14 Safeguarding Equipment	NA	6.4.12	NA	NA	NA	NA	5.5.12	5.5.12
9.7.14 Support Equipment	NA	6.4.13	NA	NA	NA	NA	5.5.13	5.5.13
9.8 Externally Provided Products and Services	NA	NA	NA	NA	NA	NA	NA	NA
9.8.1 General	NA	NA	NA	NA	NA	NA	NA	NA
9.8.2 SOPs and Procedures	NA	NA	NA	NA	NA	NA	NA	NA
9.8.3 Communicating to External Providers	NA	NA	NA	NA	NA	NA	NA	NA
9.9 Metrological Traceability	NA	6.5	NA	NA	NA	NA	5.6	5.6
9.9.1 General	NA	6.5.1	NA	NA	NA	NA	5.6.1	5.6.1
9.9.2 Traceability	NA	6.5.2	NA	NA	NA	NA	5.6.2	5.6.2
9.9.3 Reference Standards and Reference Materials	NA	6.5.3	NA	6.2.8, 6.2.9	NA	NA	5.6.3	5.6.3
9.9.4 Additional Requirements	NA	NA	NA	NA	NA	NA	5.6.4	5.6.4
9.10 Sampling	NA	7.3, 7.3.1	NA	NA	NA	NA	5.7	5.7
9.10.1 GCT's Sampling SOP	NA	7.3.2	NA	7.2.1	NA	NA	5.8.5	5.8.5
9.10.2 Sample Documentation Requirements	NA	7.3.3	NA	7.2.2, 7.2.3, 7.2.4	NA	NA	5.8.6	5.8.6
9.10.3 Sample Acceptance Requirements	NA	7.4.2	NA	NA	NA	NA	5.8.7	5.8.7
9.10.4 Sample Receipt Protocols	NA	NA	NA	NA	NA	NA	5.8	5.8
9.10.5 Sample Storage and Disposal	NA	7.4.1	NA	NA	NA	NA	NA	NA
9.11 Handling of Test Items	NA	7.4.1, 7.4.4	NA	NA	NA	NA	NA	NA
9.12 Ensuring the Validity of Results	NA	7.7.1	NA	NA	NA	NA	NA	NA
9.12.1 Performance Monitoring	NA	7.7.2	NA	NA	NA	NA	NA	NA
9.12.2 Improving Performance	NA	7.7.3	NA	NA	NA	NA	NA	NA
9.13 Reporting	NA	7.8	NA	NA	NA	NA	5.10	5.10
9.13.1 General	NA	7.8.1.1, 7.8.1.2, 7.8.1.3	NA	NA	NA	NA	5.10.1	5.10.1
9.13.2 Test Reports	NA	7.8.2	NA	NA	NA	NA	5.10.2, 5.10.3	5.10.2, 5.10.3

ANNEX A
Nominal Cross -References to ISO 17065:2012, ISO 17025:2017, 17020:2012, and TNI:2016

GCT Quality Manual Title	ISO 17065		ISO 17025		ISO 17020		TNI Standard	
	Par.		Par.		Par.		Par.	
9.13.3 Specific Requirement for Test Reports	NA		7.8.3		NA		5.10.3	
9.13.4 Requirements for Calibration Certificates	NA		7.8.4		NA		5.10.4	
9.13.5 Opinions and Interpretations	NA		7.8.7		NA		5.10.5	
9.13.6 Reporting Statements of Conformity	NA		7.8.6		6.3.1		5.10.6	
9.13.7 Testing and Calibration Results from Subcontractors	NA		NA		NA		NA	
9.13.8 Electronic Transmission of Results	NA		NA		NA		5.10.7	
9.13.9 Formatting of Reports	NA		NA		NA		5.10.8	
9.13.10 Amendments to Test Reports	NA		7.8.8		NA		5.10.9	

NA - Not Applicable