Gulf Coast Testing, LLC

Laboratory and Certification Program Quality Manual

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	PREFACE		

Introduction

The Gulf Coast Testing, LLC (GCT) Laboratory was established in 2002 at the GCT test site as an extension of its certification services. The lab 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 certification activities 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 a self-funded by its certification activities 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, BOD_5, $CBOD_5$, and TSS.

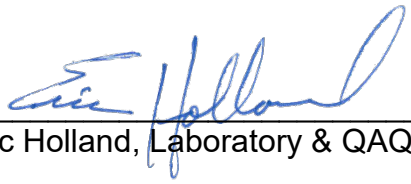
Quality Control and Quality Assurance

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 — 3/5/2020 Date

William B. Daniel IV, Program Manager — 3/5/2020 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, clients, regulatory authorities, and accreditation bodies to ensure the 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.

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 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) 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 customer. GCT reviews the activities of the supplier performed for the customer to insure 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

The 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 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 Deputy Manager and QA/QC officer interchangeably.

3.22. QA/QC Officer (Laboratory)

The 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 work with vendors, also verifying whether they follow the lab's standards. The GCT QA/QC Officer is also the Laboratory Manager and Technical Manager.

3.23. Laboratory

The laboratory is the body that calibrates and/or tests 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 in order 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 through the use of Reference Materials that are either purchased by the laboratory with a certificated 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 the 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 the 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 in order to maintain chemical and/or biological integrity prior to analysis.

3.55. Procedure

A specified way to carry out 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 the laboratory and is provided to test 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 customer; 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. 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.

3.69. 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.

3.70. 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.

4.1.2 Certification Agreement

4.1.2.1 Contract

GCT has a Quality Form called Contract for Standard Performance Evaluation the client is required to execute as part of the certification process.

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. Fulfils 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 impartial in its certification activities as evidenced through this Quality Manual, Quality Forms 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 handles all risks to impartiality through its Quality Procedures and Quality Forms.

4.2.5 Impartiality of Management

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 activates.

4.2.9 Consultancy

GCT does not market it 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.

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.

4.5 Confidentiality

4.5.1 Confidential Information of Clients

GCT maintains the confidential information of its clients. 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. 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 work with customers or representatives of clients in clarifying the customer's request and in monitoring GCT's performance in relation to the work performed, provided GCT ensures confidentiality to other customers.

4.5.2 Legal Documents

Except as required in ISO/IEC 17065, ISO/IEC 17025, TNI Standard or by law, information gained in the course of 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

In the course of 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 Program Manager (Certification and Laboratory)

a) The Program Manager is responsible for the GCT's management system.
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 handle 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.

5.1.3.2 QA/QC Manager (Certification Program)

a) The 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 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 the 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 of time 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 Laboratory Manager

a) The Laboratory is responsible for the day to day operations of the laboratory.
b) The Laboratory Manager shall be familiar with the regulatory requirements specific to the lab; and ensures all users are incompliance with those standards.
c) The Laboratory Manager oversees laboratory safety and ensures that the laboratory remains in compliance with all local, state and federal regulations.
d) The Laboratory Manager ensures the laboratory is clean and kept in an orderly manner.
e) The Laboratory Manager trains personnel in teaching techniques and safe laboratory practices.
f) The Laboratory Manager is an authorized signer of laboratory reports.

5.1.3.4 Engineering Manager

a) The 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 Laboratory Technician and Field Technician

a) The Laboratory and Field Technician shall be responsible for all the activities of the laboratory and field operations.
b) The 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 Laboratory and Field Technician shall be familiar with all the applicable Standards used by GCT and their respective requirements.
d) The 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, customers of clients, manufacturers, and governmental regulatory bodies.

6.0 RESOURCE REQUIREMENTS

6.1 Certification Body 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 a sufficient number of personnel are in place to cover its certification activities.

6.1.1.2 Qualified 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.

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 for all its employees.
b) Establish annual training goals and maintains a training record for personnel, including employees and contract personnel.
c) Record the training information in the Training Documentation Log.
d) Maintain a functional organization chart for authorization in the certification process.
e) 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 of 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) Insure 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

The GCT Laboratory shall establish and maintain procedures for the review of 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) The appropriate test and/or calibration is selected and is capable of meeting the customer's requirements

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 customer.

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 customer 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 the 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 the 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 Confidentially 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 carried out 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 complaints and appeals process is available to all clients to fairly and equitable 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 activities. Upon determination the complaint relates to the certification 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 handled 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 whom 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 ISO/IEC 9001

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 17025 and ISO 17065 are met daily for all testing and certification 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 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 and 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 customer 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 in order to give assurance that the management system is achieving its intended results.

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 customer requirements as well as statutory and regulatory requirements.

8.2.3 Responsibility to Maintain Management System

GCT Program Manager Responsibility:

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

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.

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. 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.

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.

8.4.3.3 Errors in Records

When errors occur in 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.

8.4.4 Additional 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 the 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) GCT to make all records available to the accreditation body
d) GCT's records stored on electronic media to be retrieved when requested
e) GCT to access archived information with an access log
f) GCT to retain all data necessary for the historical reconstruction including:

i. Raw data and original observations
ii. Written description of the method and associated SOP
iii. Sample ID code
iv. Data of analysis
v. Time of analysis when time critical steps are included in the analysis
vi. Instrumentation Identification
vii. Manual Calculations
viii. Laboratory Analyst Signatures
ix. All information associated with sample preparation
x. Test results
xi. Standard and Reagent information
xii. Calibration Criteria, frequency, and acceptance criteria
xiii. Data and statistical calculations
xiv. Quality control information
xv. Electronic data information
xvi. Method performance criteria

xvii. PT results
xviii. Records of demonstration for each analyst
xix. Record of names for all GCT employees signing documents
xx. GCT to record all data in ink
xxi. 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 ISO/IEC 17065 and ISO/IEC 17025.

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

Internal audits are conducted by personnel 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 in order 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
g) Reviewing the effectiveness of corrective actions

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.

8.8.2 Appropriateness of Preventive Actions

GCT generates actions appropriate to the probable impact of the potential problem.

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) Determining 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 LABORATORIES

9.1 Laboratory Quality Manual

9.1.1 Laboratory Quality Manual Responsibility

The QA/QC Manager shall have the responsibility for maintaining the 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 laboratory
d) Identification of the topics covered by the manual
e) Identification of GCT approved signatures
f) Signed and dated concurrence of the 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 the 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 the 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. The Program Manager shall communicate to the organization the importance of meeting customer 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. The Program Manager shall ensure that the integrity of the management system is maintained when changes to the management system are planned and implemented by updating the SOP's and Quality Procedures. The SOP's and Quality Procedures are available to the GCT personnel on the website and follow the Document Control and Retention Procedure. 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.

GCT has an SOP for each method and analyte. Each SOP contains the following information:

a) Identification of the method
b) Applicable Matrix
c) Limits of Detection and Quantification
d) Scope and Application
e) Summary of the Method
f) Definitions
g) Interferences
h) Safety
i) Equipment and Supplies
j) Reagents and Standards
k) Sample Collection, Preservation, Shipment and Storage
l) Quality Control
m) Calibration and Standardization
n) Procedure
o) Data Analysis and Calculations
p) Method Performance
q) Pollution Prevention
r) Data Assessment and Acceptance Criteria for QA/QC measures
s) Corrective Action for out-of-control data
t) Waste Management
u) References

v) Tables, Diagrams, flowcharts, and validation data

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 General QA/QC

9.3.1 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.

9.3.2 Uncertainty of Measurement

The extent to which the factors contribute to the total uncertainty of measurement differs considerably between tests and calibrations. The 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.

9.4 Accommodation and environmental conditions

9.4.1 Laboratory

GCT's laboratory facilitates the correct performance of the tests and/or calibrations.

9.4.2 Monitor Environmental Conditions

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

9.4.3 Effective Separation

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

9.4.4 Control of Access

GCT controls the access to the laboratory. Clients or their representatives may monitor the laboratories performance if and only if GCT can maintain the confidentiality of other clients.

9.3.5 Housekeeping

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

9.5 Test and Calibration Methods and method validation

9.5.1 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.

9.5.2 Method Selection

GCT uses test methods which comply with the Standards and meet the needs of the customer. If the customer does not specify a specific method, GCT shall select the appropriate method for the specific need of the customer. 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.

9.5.3 Laboratory Developed Methods

GCT does not use laboratory developed methods.

9.5.4 Non-Standard Methods

GCT does not use non-standard methods.

9.5.5 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.

9.5.6 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.

9.5.7 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 laboratory uses appropriate methods and procedures for all tests within its scope. These include handling, storage and preparation of samples to be tested.
b) The 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) The 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.

9.5.8 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.

9.5.8.1 Data Integrity Training

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

9.5.8.2 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.

9.5.8.3 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.

9.5.8.4 Documentation of Data Integrity

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

9.6 Equipment

9.6.1 Sufficiency of Equipment

GCT has all the items of sampling, measurement, and test equipment required for correct performance of tests and/or calibrations. If GCT lacks a specific piece of equipment for a test, GCT outsources the test.

9.6.2 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.

9.6.3 Authorized Personnel

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

9.6.4 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.

9.6.5 Maintenance of Records

GCT maintains the following records on all its equipment:

a) Identity of the item of equipment

b) Manufacturer's name, type identification, and serial number
c) Compliance of equipment with test and/or calibration
d) Current location, where appropriate
e) Manuals
f) Dates of repairs, copies of reports, and certificates of calibration, and adjustments
g) Maintenance Plan
h) Damage and/or malfunction records

9.6.6 Maintenance

GCT ensures the equipment is maintained properly.

9.6.7 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. The laboratory 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.

9.6.8 Calibration Notice

GCT has calibration stickers on the outside of all instruments requiring special calibration, including the date of the last calibration and the expiration date.

9.6.9 Equipment Removed Outside of the 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.

9.6.10 Intermediate Calibration

GCT has a procedure for all calibration requirements in every SOP.

9.6.11 Correction Factors

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

9.6.12 Safeguarding Calibration Equipment

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

9.6.13 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)

9.7 Measurement Traceability

9.7.1 General

GCT calibrates all equipment having a significant effect on the accuracy or validity of the result of the test. GCT has a calibration procedure for all equipment and processes.

9.7.2 Specific Requirements

9.7.2.1 Calibration Laboratories

GCT is not a calibration laboratory.

9.7.2.2 Testing

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

9.7.3 Reference Standards and Reference Materials

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

9.7.3.1 Reference Standards

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

9.7.3.2 Reference Materials

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

9.7.3.3 Intermediate Checks

GCT performs reference checks pursuant to its SOP's.

9.7.3.4 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.

9.7.4 Additional Requirements

9.7.4.1 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 the 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.

9.7.4.2 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.

9.8 Sampling

GCT has a sampling SOP for all its tests as well as SOP02 - Sample Receiving and Processing Procedure. In the event the customer requires additional sampling, GCT will document the additional sampling on the GCT Water Quality Log. GCT does not sample or test for evidentiary or legal purposes.

9.8.1 Additional Documentation Requirements

GCT ensures the validity of the data by:

a) Having a documented system for uniquely identifying the samples to be tested, including date and time of sampling
b) Having a laboratory code that maintains an unequivocal link with the unique field ID code assigned to each sample
c) Having the laboratory code durably marked on the sample container
d) Having the laboratory ID code entered into the laboratory records

9.8.2 Additional Sample Acceptance Requirements

9.8.2.1 Sample Acceptance

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) Customer deviation of GCT's documented sampling procedure

9.8.3 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, the laboratory shall either:

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

9.8.3.1 Sample Logbook

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

a) The record records the following:
    i. Client/Project Name
    ii. Date and Time of Laboratory Receipt
    iii. Unique Laboratory ID code
    iv. Signature or initials of GCT Laboratory Personnel

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

    i. The field ID code, which identifies each sample, shall be linked to the laboratory ID code
    ii. The date and time of sample collection shall be linked to the sample and to the date and time of receipt in the laboratory
    iii. The requested analysis shall be linked to the laboratory ID code
    iv. Any comments resulting from inspection for sample rejection shall be linked to the laboratory ID code

9.8.3.2 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.

9.8.4 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 ± 2°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.

9.9 Handling of Test Items

GCT has a SOP for the collection of samples for individual tests, including logging in the sample, storage of the sample, testing of the sample, and disposal of the sample.

9.10 Quality Assurance for Test Results

9.10.1 Quality Control

GCT has SOP's for collecting QA/QC information for each test it conducts. The data is recorded on GCT's Analytical Data Logs pursuant to the Daily Lab SOP.

9.10.2 Quality Control Deviations

GCT has SOP's for every test that specifies how the QA/QC data is to be analyzed and a procedure if the data is outside pre-defined criteria.

9.11 Reporting

9.11.1 General

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.

9.11.2 Test Reports

GCT shall include the following information on all reports not done pursuant to the Standards:

a) Title
b) Name and Address of the Laboratory
c) Location of testing if not done at the laboratory
d) Unique Identification of Test Report
e) Name and Address of the customer
f) Identification of the Method Used
g) Description of the items tested
h) Date of the receipt of the test items
i) Sampling Plan and Procedures
j) Test Results with units
k) Identification of appropriate GCT personnel
l) A qualifying statement to the effect the results only relate to the items tested

9.11.3 Information for Interpretation of Test Results

In the event the Test Report requires additional information for the interpretation of the test results, GCT will furnish the following information:

a) Deviations from, additions to, or exclusions from the test method
b) A statement of compliance or non-compliance with requirements
c) If necessary, a statement on the estimated uncertainty of measurement
d) If necessary, Opinions and Interpretations
e) Any additional required to interpret the results or requested by the client
f) Date of sampling
g) Type of material sampled
h) Location of Sampling
i) Reference to sampling plan and procedures used

9.11.4 Calibration Certificates

GCT does not issue calibration certificates.

9.11.5 Opinions and interpretations

In the event GCT issues opinions and interpretations, they will be clearly identified and labeled in the test report.

9.11.6 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.

9.11.7 Electronic Transmission of Results

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

9.11.8 Formatting of Reports

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

9.11.10 Amendments to Test Reports

Material amendments to the test report made only be made in the form of a further document. Such reports shall meet all the requirements of ISO/IEC 17065 and ISO/IEC 17025. In the event an entire new report is issued, it will be uniquely identified.

ANNEX A – ORGANIZATION CHART

Published 2020.03.05
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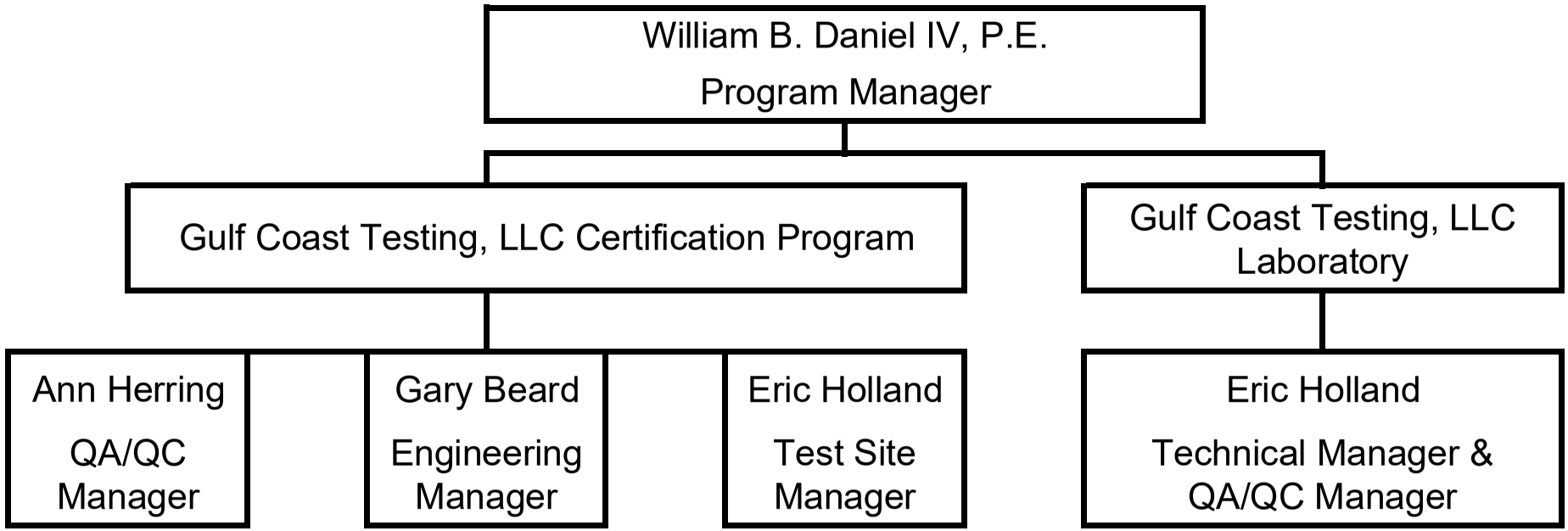
Gulf Coast Testing, LLC Organization Chart



ANNEX B – JOB QUALIFICATIONS

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

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

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

Method	Accreditation	Method Number
$BOD_5/CBOD_5$	Standard Methods	5210B
TSS	Standard Methods	2540D
pH	EPA	9040C

ANNEX D - NOMINAL CROSS-REFERENCE 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	ISO 17065	ISO 17025	ISO 17020	TNI Standard
Title	Par.	Par.	Par.	Par
1.0 Scope	**1.0**	**1.0**	**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
3.3 Product	3.3	NA	NA	NA
3.4 Process	3.4	NA	NA	NA
3.5 Service	3.5	NA	NA	NA
3.6 Certification Requirement	3.6	NA	NA	NA
3.7 Product Requirement	3.7	NA	NA	NA
3.8 Certification Scheme	3.8	NA	NA	NA
3.9 Scopes of Certification	3.9	NA	NA	NA
3.10 Scheme Owner	3.10	NA	NA	NA
3.11 Certification Body	3.11	NA	NA	NA
3.12 Impartiality	3.12	NA	NA	NA
3.13 Standard	3.13	NA	NA	NA
3.14 Supplier	NA	NA	NA	NA
3.15 Test	NA	NA	NA	NA
3.16 Conformity	NA	NA	NA	NA
3.17 Non Conformity	NA	NA	NA	NA
3.18 Quality Manual	NA	NA	NA	NA
3.19 Quality Assurance Officer	NA	NA	NA	NA
3.20 Exception	NA	NA	NA	NA
3.21 Laboratory	NA	NA	NA	NA
3.22 On Site Testing	NA	NA	NA	NA
3.23 Qualified personnel	NA	NA	NA	NA
3.24 Verification	NA	NA	NA	NA
4.0 General Requirements	**4.0**	**4.0**	**4.0**	**4.0**
4.1 Legal and Contractual Matters	4.1	4.1	NA	4.1
4.1.1 Legal Responsibility	4.1.1	4.1.1	NA	4.1.1
4.1.2 Certification Agreement	4.1.2	NA	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	NA	NA	NA
4.2.1 Impartiality	4.2.1	4.1.4	4.1.1	4.1.4
4.2.2 Responsibility	4.2.2	NA	4.1.2	NA
4.2.3 Risks to Impartiality	4.2.3	NA	4.1.3	NA
4.2.4 Minimizing Risk to Impartiality	4.2.4	NA	4.1.4	NA
4.2.5 Impartiality of Management	4.2.5	4.15	4.1.5	4.15
4.2.6 GCT Consultants and Impartiality	4.2.6	NA	4.1.6 a)	NA
4.2.7 Other Entities	4.2.7	4.1.4	4.1.6 b)	4.1.4
4.2.8 Separate Legal Entities	4.2.8	4.1.4	4.1.6 c)	4.1.4
4.2.9 Consultancy	4.2.9	NA	NA	NA
4.2.10 Prohibition of Consultancy	4.2.10	NA	NA	NA
4.2.11 Response to Risks of Impartiality	4.2.11	NA	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	NA	NA	NA
4.5 Confidentiality	4.5	NA	4.2	NA
4.5.1 Confidential Information of Clients	4.5.1	4.7.1	4.2.1	4.7.1
4.5.2 Legal Documents	4.5.2	NA	4.2.2	NA
4.5.3 Additional Client Information	4.5.3	NA	4.2.3	NA
4.6 Publicly Available Information	4.6	NA	7.5.2	NA
4.7 Procurement	4.7	4.6	6.2.11	4.6
4.7.1 Procurement Policy	NA	4.6.1	NA	4.6.1
4.7.2 Purchased Supplies	NA	4.6.2	NA	4.6.2

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

GCT Quality Manual	ISO 17065	ISO 17025	ISO 17020	TNI Standard
Title	**Par.**	**Par.**	**Par.**	**Par**
4.7.3 Documents	NA	4.6.3	NA	4.6.3
4.7.4 Critical Supplies	NA	4.6.4	NA	4.6.4
5.0 Structural Requirements	**5.0**	4.1.5	NA	4.1.5
5.1 Organization Structure and Top Management	5.1	4.1.5	5.2.2	4.1.5
5.1.1 Certification and Impartiality	5.1.1	4.1.5	5.2.1	4.1.5, 4.2.6
5.1.2 Organizational Structure	5.1.2	4.1.5	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	4.1.5	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	4.7.2	NA	4.7.2
6.0 Resource Requirements	**6.0**	NA	NA	NA
6.1 Certification Body Personnel	6.1	4.1.2, 4.1.5, 4.2.6, 5.2	NA	4.1.2, 4.1.5, 4.2.6, 5.2
6.1.1 General	6.1.1	4.1.2, 5.2.5	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	5.2.2, 5.2.4	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	4.1.5, 5.2.3	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	4.1.2	6.2.1, 6.2.2, 6.2.3, 6.2.4	4.1.2
6.2.2 External Resources	6.2.2	4.4.3, 4.4.4, 4.5, 4.5.1,4.5.2, 4.5.3, 4.5.4	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**	4.4	**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	4.4.1	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	4.4.2	NA	4.4.2
7.3.1 Review of Application Information	7.3.1	4.7.1	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 Testing	NA	4.9, 4.9.1, 4.9.2	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

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

GCT Quality Manual	ISO 17065	ISO 17025	ISO 17020	TNI Standard
Title	**Par.**	**Par.**	**Par.**	**Par**
7.6.5 Personnel with entities under Organizational Control	7.6.5	NA	NA	NA
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 during Annual Compliance Audits	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	4.3.3, 4.13, 4.13.1	NA	4.3, 4.3.3, 4.13, 4.13.1
7.12.1 Records Retention Policy	7.12.1	4.13.1, 4.13.2	NA	4.3, 4.13.1, 4.13.2
7.12.2 Confidentially of Records	7.12.2	4.1.5, 4.13.1	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	4.13.2	NA	4.13.2
7.13 Complaints and Appeals	7.13	4.8	NA	4.8
7.13.1 Complaint and Appeals Process	7.13.1	4.8	7.5.1, 7.6.1	4.8
7.13.2 Complaints and Appeals Applicability	7.13.2	4.8	7.5.3	4.8
7.13.3 Formal and Informal Complaints and Appeals	7.13.3	4.8	NA	4.8
7.13.4. Information for Complaints and Appeals	7.13.4	4.8	7.6.2	4.8
7.13.5. Decisions on Complaints and Appeals	7.13.5	4.8	7.5.4	4.8
7.13.6. Conflicts of Interest	7.13.6	4.8	7.13.4	4.8
7.13.7. Notice	7.13.7	4.8	NA	4.8
7.13.8. Notification of Outcome	7.13.8	4.8	7.5.5, 7.6.3, 7.6.5	4.8
7.13.9. Resolution	7.13.9	4.8	NA	4.8
8.0 Management System Requirements	**8.0**	4.2	NA	**4.0**
8.1. Options	8.1.	4.2.1	NA	4.2.1
8.1.1. GCT is an "Option A" CB pursuant to ISO/IEC 17065.	8.1.1.	4.2.1	8.1.1	4.2.1
8.1.2 Management System Information	8.1.2	4.2	8.1.2	4.2
8.1.3. ISO/IEC 9001	8.1.3.	1.0	8.1.3	1.0
8.2. General Management System Documentation	8.2.	4.2	NA	4.2
8.2.1. Policies and Objectives	8.2.1.	4.2.1	8.2.1	4.2.1
8.2.2. Commitment to Management System	8.2.2.	4.2.2, 4.2.3, 4.2.4, 4.10	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.	4.2.1, 4.2.7	8.2.3	4.2.1, 4.2.7
8.2.4. Documentation of Management System	8.2.4.	4.2.2, 4.2.5	8.2.4	4.2.2, 4.2.5
8.2.5 Access to Documents	8.2.5	4.2.1	8.2.5	4.2.1
8.3. Control of Documents	8.3.	4.3	8.3	4.3
8.3.1. Records Retention Procedure	8.3.1.	4.3, 4.13	8.3.1	4.3, 4.13
8.3.2. Records and Documents Policy	8.3.2.	4.3, 4.13	8.3.2	4.3, 4.13

GCT GULF COAST TESTING, LLC

ANNEX A

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

GCT Quality Manual	ISO 17065	ISO 17025	ISO 17020	TNI Standard
Title	**Par.**	**Par.**	**Par.**	**Par**
8.4. Control of Records	8.4.	4.3.1, 4.13	8.4	4.3.1, 4.13
8.4.1. Records and Documents Control Policy	8.4.1.	4.3.2, 4.13	8.4.1	4.3.2, 4.13
8.4.2. Records and Documents Retention Policy	8.4.2.	4.3.2, 4.13	8.4.2	4.3.2, 4.13
8.4.3 Laboratory Technical Records	NA	4.13.2	NA	4.13.2
8.4.4 Additional Data Requirements	NA	NA	NA	4.13.3
8.5. Management Review	8.5.	4.1.5, 4.16, 4.2.2, 8.2	8.5	4.15, 4.1.6, 4.2.2
8.5.1. General	8.5.1.	4.15	8.5.1	14.5
8.5.2. Review of Inputs to Management Review	8.5.2.	4.1.6, 4.2.7, 4.10, 4.15.1	8.5.2	4.1.6, 4.2.7
8.5.3. Review Outputs	8.5.3.	4.15.2	8.5.3	4.15.2
8.5.4 Data Integrity Investigations	NA	NA	NA	4.16
8.6. Internal Audits	8.6.	4.14	8.6	4.14
8.6.1. Internal Audit Procedure	8.6.1.	4.14.1	8.6.1	4.14.1
8.6.2. Audit Assurance Procedure	8.6.2.	4.14.3	8.6.2	4.14.3
8.6.3. Audit Frequency	8.6.3.	4.14.1	8.6.3, 8.6.4	4.14.1
8.6.4. Audit Requirements and Outcomes	8.6.4.	4.14.1, 4.14.2, 4.14.3, 4.14.4	8.6.5	4.14.1, 4.14.2, 4.14.3, 4.14.4
8.6.5 Notification of Clients	NA	NA	8.6.5	14.14.5
8.7. Corrective Actions	8.7.	4.11	8.7	4.11
8.7.1. Corrective Actions	8.7.1.	4.11.1	8.7.1	4.11.1
8.7.2. Nonconformities	8.7.2.	4.11.2	8.7.2	4.11.2
8.7.3. Appropriateness of Corrective Actions	8.7.3.	4.11.3	8.7.3	4.11.3
8.7.4. Corrective Action Procedure Requirements	8.7.4.	4.11.4	8.7.4	4.11.4
8.7.5 Additional Audits	NA	8.7.5	8.7.4	8.7.5
8.7.6 Dcoumented 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.	4.12	8.8	4.12
8.8.1. Preventative Actions	8.8.1.	4.12.1	8.8.1	4.12.1
8.8.2. Appropriateness of Preventative Actions	8.8.2.	4.12.1, 4.12.2	8.8.2	4.12.1, 4.12.2
8.8.3. Preventative Action Procedure Requirements	8.8.3.	4.12.2	8.8.3	4.12.2
9.0 Technical Requirements	NA	5.0	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	NA	NA	4.2.8.5
9.3 General QA/QC	NA	5.1	NA	5.1
9.3.1 Correctness and Reliability	NA	5.1.1	NA	5.1.1
9.3.2 Uncertainty of Measurement	NA	5.1.2	NA	5.1.2
9.4 Accommodation and environmental conditions	NA	4.1.3, 5.1,5.3	NA	4.1.3, 5.3
9.4.1 Laboratory	NA	5.3.1	NA	5.3.1
9.4.2 Monitor Environmental Conditions	NA	5.3.2	NA	5.3.2
9.4.3 Effective Separation	NA	5.3.3	NA	5.3.3
9.4.4 Control of Access	NA	5.3.4	NA	5.3.4
9.4.5 Housekeeping	NA	5.3.5	NA	5.3.5
9.5 Test and Calibration Methods and method validation	NA	5.4	6.2.5, 6.2.6, 6.2.7, 6.2.8, 6.2.9, 6.2.10	5.4
9.5.4 General	NA	5.4.1	NA	5.4.1
9.5.2 Selection of Methods	NA	5.4.2	NA	5.4.2
9.5.3 Laboratory Developed Methods	NA	5.4.3	NA	5.4.3
9.5.4 Non-Standard Methods	NA	5.4.4	NA	5.4.4
9.5.5 Validation of Methods	NA	5.4.5	NA	5.4.5
9.5.6 Estimation of Uncertainty	NA	5.4.6	NA	5.4.6
9.5.7 Control of Data	NA	5.4.7	NA	5.4.7
9.5.8 Data Integrigy	NA	NA	NA	4.2.8.1
9.6 Equipment	NA	5.5	NA	5.5
9.6.1 Sufficiency of Equipment	NA	5.5.1	NA	5.5.1
9.6.2 Accuracy	NA	5.4.2	NA	5.4.2
9.6.3 Authorized Personnel	NA	5.5.3	NA	5.5.3
9.6.4 Identification of Equipment	NA	5.5.4	NA	5.5.4

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

GCT Quality Manual	ISO 17065	ISO 17025	ISO 17020	TNI Standard
Title	Par.	Par.	Par.	Par
9.6.5 Maintenance of Records	NA	5.5.5	6.2.15	5.5.5
9.6.6 Maintenance	NA	5.5.3	6.2.9	5.5.3
9.6.7 Taking equipment out of service	NA	5.5.7	6.2.14	5.5.7
9.6.8 Calibration Notice	NA	5.5.8	NA	5.5.8
9.6.9 Equipment Removed Outside of the Laboratory	NA	5.5.9	NA	5.5.9
9.6.10 Intermediate Calibration	NA	5.5.10	NA	5.5.10
9.6.11 Correction Factors	NA	5.5.11	NA	5.5.11
9.6.12 Safeguarding Calibration Equipment	NA	5.5.12	NA	5.5.12
9.6.13 Support Equipment	NA	NA	NA	5.5.13
9.7 Measurement Traceability	NA	5.6	NA	5.6
9.7.1 General	NA	5.6.1	NA	5.6.1
9.7.2 Specific Requirements	NA	5.6.2	NA	5.6.2
9.7.3 Reference Standards and Reference Materials	NA	5.6.3	6.2.8, 6.2.9	5.6.3
9.7.4 Additional Requirements	NA	NA	NA	5.6.4
9.8 Sampling	NA	5.7	NA	5.7
9.8.1 Additional Documentation Reaquirements	NA	NA	7.2.1	5.8.5
9.8.2 Additional Sample Acceptance Requirements	NA	NA	7.2.2, 7.2.3, 7.2.4	5.8.6
9.8.3 Sample Receipt Protocols	NA	NA	NA	5.8.7
9.8.4 Handling of Test Items	NA	5.8	NA	5.8
9.9 Quality Assurance for Test Results	NA	5.9	NA	5.9
9.9.1 Quality Control	NA	5.9.1	NA	5.9.1
9.9.2 Quality Control Deviations	NA	5.9.2	NA	5.9.2
9.10 Reporting	NA	5.10	NA	5.10
9.10.1 General	NA	5.10.1	NA	5.10.1
9.10.2 Test Reports	NA	5.10.2,5.10.3	NA	5.10.2,5.10.3
9.10.3 Information for Interpretation of Test Results	NA	5.10.3	NA	5.10.3
9.10.4 Calibration Certificates	NA	5.10.4	NA	5.10.4
9.10.5 Opinions and interpretations	NA	5.10.5	NA	5.10.5
9.10.6 Testing and Calibration Results from Subcontractors	NA	5.10.6	6.3.1	5.10.6
9.10.7 Electronic Transmission of Results	NA	5.10.7	NA	5.10.7
9.10.8 Formatting of Reports	NA	5.10.8	NA	5.10.8
9.9.10 Amendments to Test Reports	NA	5.10.9	NA	5.10.9
9.10 Quality Assurance for Test Results	NA	NA	NA	NA
9.11 Reporting	NA	NA	6.3.1, 6.3.2, 6.3.3, 6.3.4	NA

NA - Not Applicable