GEX Corporation

4437 SW Cargo Way,
Palm City, FL 34990 U.S.A.

QUALITY MANUAL

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1.0 MANAGEMENT SYSTEM

1.1 Purpose

The purpose of this Quality Manual outlines the policies and requirements of the GEX quality management system. The Quality Management System (QMS) described in this manual was implemented according to the ISO 9001 and ISO 17025 International Standard requirements. This manual describes key components of the QMS and references its supporting policies and procedures.

1.2 Background

GEX (Gamma / E-Beam / X-ray) Corporation is a privately held corporation that was established in 1991. GEX is the world leader in providing total DOSIMETRY SOLUTIONS for industrial users, and continuously work with radiation equipment systems manufacturers, in-house users, and contract irradiation facilities around the world to develop complete dosimetry systems designed to meet end user requirements. GEX's range of product and service offerings include routine dosimeter products, complete dosimetry systems (for B3, FWT, CTA, PMMA, and Alanine), dosimeter batch calibration services, and radiation and temperature indicators.

1.3 Scope of Quality Management System Certification

The scope of the quality management system is defined below as it applies to GEX Corporation administrative office and manufacturing facility located at 4437 SW Cargo Way, Palm City, FL 34990, U.S.A:

ISO 9001 Quality Management System scope:

"Design, provision, installation, and qualification of Dosimetry Systems and Accessories (includes hardware and software) for Radiation Processing, and Dosimetry System Calibration Services."

ISO 17025 Accredited Calibration Laboratory scope:

"Provision of Transfer-Standard Alanine Dosimetry"

ISO 52628:2013(E) definition of Transfer-Standard Dosimetry System: dosimetry system used as an intermediary to calibrate other dosimetry systems

1.4 ISO standards and Guidelines

Below is the list of International Organization for Standardization (ISO) Standards and Guidelines applicable to the GEX Quality Management System.

ISO 9001 QMS	Requirements
ISO 17025 QMS	General requirements for the competence of testing and calibration laboratories
NIST Handbook 150	NVLAP Procedures and General Requirements, (Annex A). Used as the policy and procedure for controlling the use of the term "NVLAP", the NVLAP logo, and NVLAP symbol.
NIST Handbook 150-2	NVLAP Calibration Laboratories. Presents the technical requirements and guidance for the accreditation of the GEX lab under the NAVLAP Calibration Laboratories LAP.

1.5 GEX Quality Policy

GEX's quality management system is guided by our overall Quality Policy:

"Delivering solutions that fulfill customer requirements and exceed customer expectations with a commitment to continual improvement and meeting quality objectives."

GEX's leadership is committed to creating and sustaining an organization that anticipates, meets, and exceeds the expectations of its customers. GEX is committed to providing excellent customer service and value to our customers by continually improving our work processes and the capabilities of our employees.

The Quality Policy is communicated to all employees through training and regular communications directed by leadership. The continuing suitability of the Quality Policy is reviewed annually at management review to ensure relevancy and alignment with the context of the organization and strategic plan.

GEX has embraced continuous improvement with increasing efficiency and enhancing quality by creating a cross-functional team to detect and prevent defects, and to identify, prioritize, and implement the processes that need improvement. The results are measured and monitored to ensure effectiveness and sustainability.

1.6 Quality Objectives

The quality objectives that have been implemented to support our quality policy consist of:

✓Continually improving the accuracy and efficiency of operational processes.

✓Driving continuous improvement by reducing nonconformities, continuing to drive supplier improvements, effectively incorporating process and product innovations.

✓Continually improving the customer experience.

1.7 Key Elements of the GEX Quality Management System

1.7.1 The Organization and its Context

External and internal issues that are relevant to the purpose and strategic direction of GEX and affect the ability to achieve the intended result(s) of the QMS are determined, monitored, and reviewed during annual performance of management review and internal audit.

Topics include but are not limited to product/equipment updates, infrastructure, environment, personnel changes, updates on services provided, new methods (i.e., automation, collection, categories of information, etc.), testing facilities, contractors/sub-contractors/vendors, technological/software updates, competitive analysis, and company personnel.

Figure 1 lists the External and Internal factors that can potentially affect GEX's ability to meet objectives of the QMS:

Internal Factors	**Affects**
Hours of operation	Structure, complexity
Nature of business is for profit type (vs. nonprofit)	All
Array of education backgrounds of the employees	Competence
Entire business is within scope	Complexity
Company size	Structure
Worldwide territory of business	Risks, complexity, NOIP
External Factors	**Affects**
Market composition of customer size and ownership	Outputs
Medical Device sterilization dosimetry requirements	Structure, risks, NOIP, outputs
Medical Device and Pharmaceutical customers	Risks, NOIP

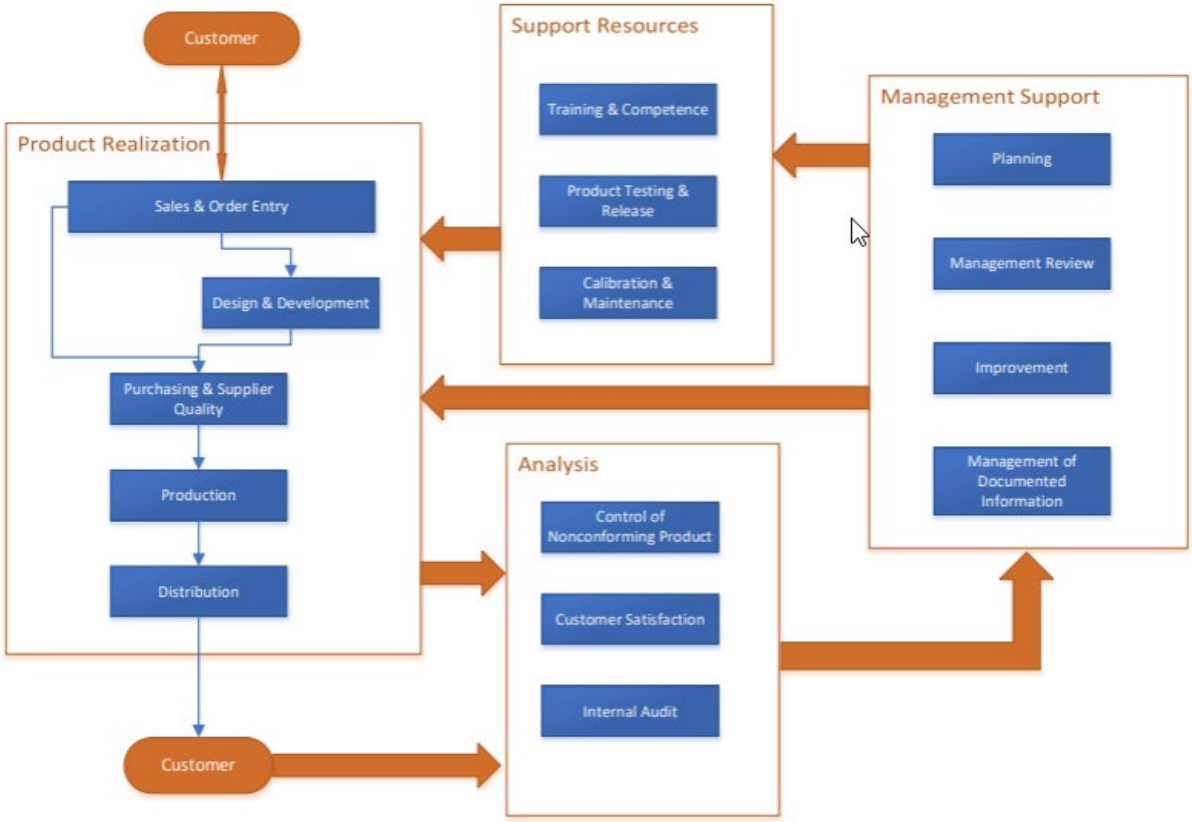
*NOIP definition: needs of interested parties such as customers, shareholders, and vendors
*Outputs: products and services and related documentation

1.7.2 Interested Parties

Interested parties are stakeholders who can pose a significant risk to organizational sustainability if their needs and expectations are not met. The stakeholders are determined due to their effect or potential effect on the ability for GEX to consistently provide products and services that meet customer and applicable statutory and regulatory requirements. GEX's interested parties have a diverse set of needs and expectations. Both internal and external interested parties have been identified and evaluated to determine their specific requirements. GEX leadership monitors and reviews information about the interested parties and their requirements during management review. Interested parties include shareholders (owners), customers, regulatory agencies, external providers and sub-contractors, and employees.

1.7.3 Quality Management System Processes

The key processes and interactions to support the effective operation of the QMS to ensure product and service quality are outlined in Figure 2:



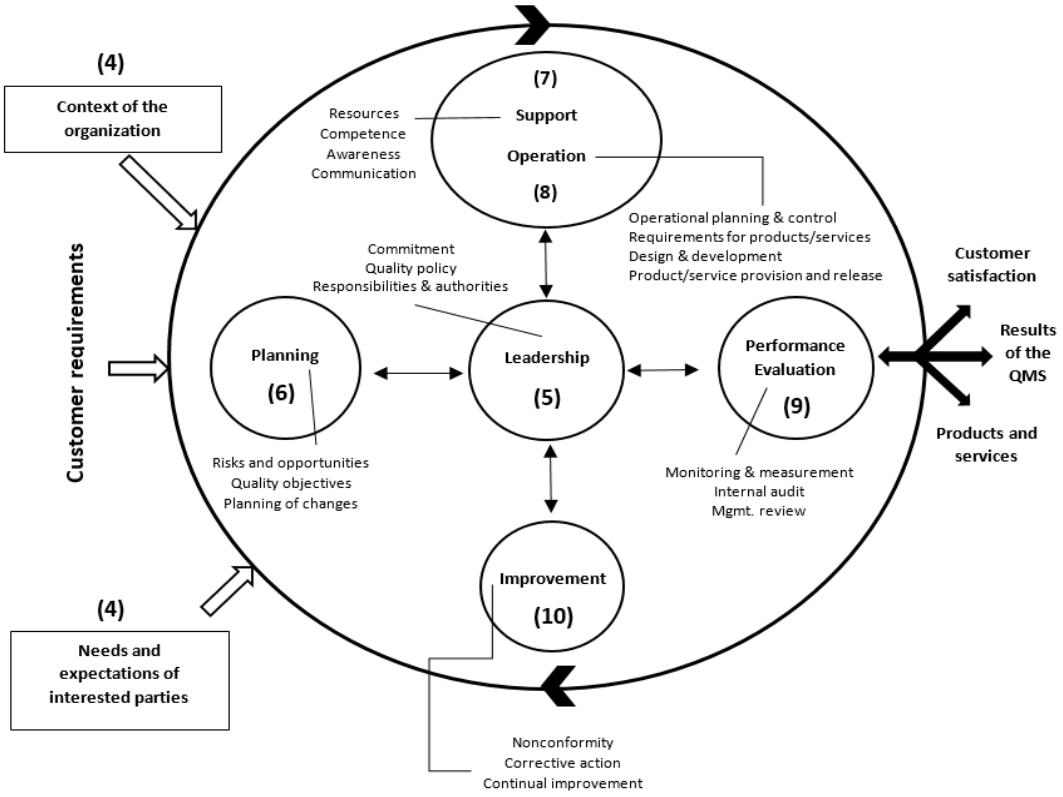
The QMS processes are defined with quality system procedures that provide an overview of the process and policies. Procedures are supported with related work instructions, specifications, forms, and other documented information as necessary to maintain the effectiveness of the processes and the overall QMS.

Figure 2 demonstrates how the Plan-Do-Check-Act cycle applies to the Quality Management System processes:

Figure 2

QUALITY MANAGEMENT SYSTEM PROCESSES DIAGRAM
(Based on **Plan-Do-Check-Act)**

*Note: numbers in brackets refer to the clauses in ISO 9001:2015.



1.7.4 Communication

Communication relevant to the QMS is determined and maintained as required. See Figures 3 and 4 below.

Figure 3

EXTERNAL COMMUNICATION

EXTERNAL COMMUNICATION					
External Information Communicated (what)	**ISO 9001:2015 Reference**	**Method (how)**	**When to Communicate**	**Audience (with whom)**	**Communicator (who)**
Quality Policy	5.2.2c	Quality Manual Website	As requested	Relevant interested parties	Quality Manager
Information relating to products and services	8.2.1a	Website, Business Development team	Customer meetings/calls	Current and potential customers	Customer Service & Sales Team
Handling enquiries, contracts or orders, including changes	8.2.1b	Email, phone, meetings with customers	As requested	Current and potential customers	Customer Service & Sales Team
Obtaining customer feedback relating to products and services, including customer complaints	8.2.1c	Email, phone, meetings with customers, customer surveys	As required (when contacted via email/phone) Yearly (customer surveys)	Customers	Customer Service, Sales Teams, & Quality Manager
Handling or controlling customer property	8.2.1d	Email, phone	As needed	Current and potential customers	Operations Manager & Customer Service
Establishing specific requirements for contingency actions, when relevant.	8.2.1e	Email, phone, meetings with customers	As needed	Customers	Customer Service & Quality Manager
Requirements for externally provided processes, products and services	8.4.3	Email or phone	As needed	External providers	Operations Manager, Sales Team, & Purchasing Team
Loss, damage, or unsuitable condition of customer property	8.5.3	Email or phone	As needed	Customers	Customer Service, Quality Manager, & Sales Team
Loss, damage, or unsuitable condition of external provider's property	8.5.3	Email or phone	As needed	External providers	Operations Manager, Purchasing Team
Nonconforming outputs	8.7.1c	Email or phone	As needed	Customers	Quality Manager, Sales Team, Customer Service

Figure 4
INTERNAL COMMUNICATION

INTERNAL COMMUNICATION					
Internal Information Communicated (what)	**ISO 9001:2015 Reference**	**Method (how)**	**When to Communicate**	**Audience (with whom)**	**Communicator (who)**
Quality Policy	**5.2.2b, 7.3a**	Quality Manual, posted in Operations and in break room, meetings, and emails.	When employee start working for GEX On-going basis.	Employees	Quality Manager
Quality Objectives	**6.2.1f, 7.3b**	QF-54-01 Quality Objective record. Weekly Management Reviews, meetings, and emails.	When employee start working for GEX On-going basis.	Employees	Management Team
The importance of effective quality management and of conforming to the quality management system requirements	**5.1.1f**	Quality manual, emails, weekly meetings	When employee start working for GEX On-going basis.	Employees	Quality Manager
Relevant quality management system responsibilities and authorities	**5.3**	Org. Chart, Quality Manual, meetings	When employee start working for GEX On-going basis.	Employees	Top Management
Performance of the QMS	**5.3c**	Customer Feedback/Surveys, meetings	On-going basis.	Employees more details for Top Management	Quality Manager
Contribution to the effectiveness of the quality management system, including the benefits of improved performance;	**7.3c**	Meetings	On-going basis.	Employees more details for Top Management	Quality Manager
The implications of not conforming with the quality management system requirements	**7.3d**	Nonconforming Products, Corrective Actions and Complaint Log	On-going basis.	Employees more details for Top Management	Quality Manager
Changes to product requirements	**8.2.4**	Meetings, ECO	On-going basis.	Top Management	Quality Manager
Internal audit results	**9.2.2d**	Management Review and meetings	As needed	Employees more details for Top Management	Quality Manager
External audit results	**9.2.2d**	Management Review and meetings	As needed	Employees more details for Top Management	Quality Manager

2.0 QUALITY SYSTEM MANAGEMENT AND RESPONSIBILITY

2.1 Overview

Responsibilities for quality are specified not only for compliance with policies and procedures but also so that decisions are based on principles that ensure quality. Documented responsibilities ensure that expected behaviors are communicated throughout the company rather than left to interpretation.

2.2 Quality duties, responsibilities, and authority

Management is responsible for oversight of the quality system and determines and provides the knowledge, resources, environment, and infrastructure needed for the establishment, implementation, maintenance, and continual improvement of the QMS. Executive Management ensures that the company avoids derogatory or questionable activities that would diminish confidence in its competence, impartiality, judgment, or operational integrity. Business Continuity Planning ("BCP") is available to ensure that the business has strategic and tactical plans to follow should there be a significant disruption to the business.

The Quality Manual is reviewed annually for adequacy by management who are responsible for ensuring changes are accurate, approved, instituted, and implemented. A company organization chart is a visual aid for the responsibilities and reporting structure. The President fully supports the Quality Assurance Manager in the execution of assigned quality responsibilities.

The Quality Assurance Manager is responsible for the establishment, implementation, control, and maintenance of the quality system, and ensuring the overall effectiveness of the QMS.

The Quality Assurance Manager has the authority to:

- Stop work when continuing work may adversely affect quality.
- Prevent the use of equipment or materials that may adversely affect quality.
- To direct the removal and replacement of any nonconforming work, equipment, or material by GEX, any subcontractor, or any supplier.
- Suspend work and/or supply of materials by any staff member, subcontractor personnel, or supplier as deemed necessary to assure quality results.

The Quality Assurance Manager, process owners, and department managers are responsible for:

- Ensuring that the QMS conforms to ISO requirements.
- Ensuring that the processes are delivering their intended outputs.
- Reporting on the performance of the QMS and opportunities for improvement (OFIs).
- Ensuring the promotion of customer focus throughout the organization.
- Ensuring that the integrity of the QMS is maintained when changes to the QMS are planned and implemented.

All employees have quality responsibilities that include:

- Conformance to quality, product/service, and customer requirements.
- Compliance with all provisions of the GEX Quality Manual.
- Understanding the Quality Policy.
- Understanding the implications of not conforming with the QMS requirements.
- Understanding the benefits of an improved QMS performance.

The Laboratory Manager is responsible for administering the NIST Handbook 150 and NIST Handbook 150-2 requirements within the Laboratory Department. The Laboratory Manager and Quality Assurance Manager are responsible for ensuring compliance with NIST Handbook 150 and NIST Handbook 150-2. Approved Signatories are responsible for the technical content, review, and approval of laboratory calibration reports.

2.3 Quality System Performance Measures

Company-wide quality performance measures evaluate the effectiveness of the Quality System. The following indicators are the primary measures of quality performance:

- Nonconformances and complaint data analysis from audits and management review.
- Customer satisfaction feedback.

Management representatives evaluate GEX quality performance and set improvement goals at least annually.

GEX obtains feedback on whether customer quality expectations are being met, and to what extent. The customer satisfaction data is analyzed to determine opportunities for improvement and address any items of customer dissatisfaction.

2.4 Documented Information

Documented information encompasses both documents and records and serves as a tool for transmitting and communicating essential details within the company, providing evidence that planned activities have been executed as intended, and helps to disseminate and preserve the GEX's knowledge and experiences. GEX demonstrates the effective planning, operation, and control of processes through documented information. Documented information is in paper, electronic, and media format, and is controlled appropriately.

2.4.1 QMS Documents

The QMS documents are uniquely identified and structured in the following way:

-Organizational chart

-Process maps, flow charts, and/or process descriptions

-Procedures

-Work and/or test instructions

-Specifications

-Forms

3.0 OPERATIONAL PLANNING AND CONTROLS

3.1 Overview

Operational planning and control are integral to achieving effective QMS operation and meeting customer expectations. It involves systematic planning for day-to-day activities within the management system, and encompasses how an organization plans, implements, and controls the processes necessary to meet QMS requirements. During the planning phase, risks, opportunities, and other relevant elements are identified. The control of operational processes must ensure that their operational processes align with quality objectives and contribute to meeting customer requirements. This includes maintaining consistency, implementing necessary controls, and monitoring ongoing activities.

The overall process consists of the following:

- Plan: align the processes with the overall business strategy. Determine the requirements and establish criteria.
- Implement: ensure that the QMS is integrated into business operations.
- Control: thoroughly manage operations, considering desired outcomes and potential risks and opportunities.
- Document that the processes have been completed as planned and to demonstrate the conformity of products and services to their requirements.

3.2 Risk management

Integrating risk and opportunity management into operational planning proactively addresses uncertainties and leads to improved quality and performance. It is the process of identifying, assessing, and addressing opportunities that could affect the QMS and business objectives. The company has an integrated risk-based approach and considers aspects such as quality planning, design, monitoring and measurement, and problem resolution.

3.3 Change control

The company has adopted the seven-step change management process (Identify the Need for Change, Define the Purpose and Potential Impact, Plan the Change, Implement the Change, Monitor and Evaluate, Review and Adjust, Document the Change).

When it has been determined that there is a need for changes to the QMS, the changes are carried out in a planned manner to ensure the QMS remains robust, adaptable, and aligned with organizational goals.

The key considerations during planning are as follows:

- Purpose and Consequences: Understand why the change is necessary and consider both the positive and negative consequences of the change.
- Maintaining QMS Integrity: Ensure that the changes alight with customer requirements, enhance satisfaction, and promote continual improvement.
- Resource Availability: Assess the resources needed for the change and ensure they are available within the required time limit.
- Responsibilities and Authorities: If there are new or changed responsibilities, incorporate them into the plan to ensure sustained improvement after implementation.

3.4 Customer communication

Communications with customers in relation to products and services include:

- Product and Service Information: Providing clear information about the products and services offered, understanding the customer requirements, and ensuring the products and services offered can be met.
- Handling of Enquiries, Contracts, and Orders: Ensuring smooth interactions during the entire process, including any changes, and communicating change orders to relevant personnel.
- Customer Feedback and Complaints: Gathering feedback related to products and services, including complaints.
- Handling Customer Property: Responsibly managing any property provided by the customer.
- Contingency Actions: Establishing specific requirements for contingency situations when relevant.

3.5 Design and development

The overall process ensures that the company creates products and services that meet requirements while maintaining effective processes. It encompasses transforming requirements (such as specifications, statutory requirements, and specific or implied customer requirements) into specified product or service characteristics. The procedure ensures that all design and development interfaces among different organizational functions and groups are defined and responsibly managed to ensure effective communication and clear assignment of responsibilities. The process includes design and development planning, inputs, controls, outputs, and changes. When the design and development process is outsourced, the supplier must meet the requirements of the procedure and provide objective evidence that the requirements were met.

3.6 Externally provided processes, products, and services

The process ensures that processes, products, and services obtained from external sources align with the company's quality objectives and enhances overall product or service quality within the QMS. Controls are applied in the following scenarios:

- When the products and services are intended for incorporation into GEX's own products and services.
- When they are provided directly to customers by the external provider on behalf of GEX.
- When a process (or part of a process) is provided by an external provider due to a decision by GEX (e.g., subcontracted processes).

The criteria for evaluation, selection, and monitoring of performance, and re-evaluation of external providers is determined and documented, including any necessary actions arising from evaluations. Examples of externally provided processes, products, or services include but are not limited to purchase of raw materials, components, or subassemblies, subcontracted specialist processes, instrument calibration services, and equipment preventive maintenance and servicing.

3.7 Measuring and monitoring resources

The process for measuring and monitoring resources ensures conformity for all products and services and establishes methods for using, calibrating, and maintaining monitoring and measuring equipment and/or resources as well as associated record keeping and traceability. This includes making sure that equipment is valid, up to date, and calibrated and working properly. All measurements taken must be accurate and recorded for monitoring purposes.

3.8 Production and Service Provision

Activities are executed to provide the product or service under controlled conditions. The key elements of controlled conditions include:

- Documented information for the products and services.
- Suitable monitoring and measurement resources, including equipment.
- Appropriate infrastructure and environment.
- Competent personnel.
- Validation of the ability to achieve results.
- Actions to prevent human error.
- Activities controlling product release, delivery, and post-delivery.

3.8.1 Identification and Traceability

Materials, components, and finished products are uniquely identified throughout all stages of product realization and when in storage. The identification of items with unique control numbers is used to facilitate corrective actions. Traceability ensures the ability to track elemental parts within items, especially when there is a failure of an internal component.

3.8.2 Property Belonging to Customers or External Providers

The company exercises care with property belonging to customers or external providers (supplier / subcontractors) while it is being used or under the control of GEX. It is identified, verified, protected, and safeguarded when being used or under the control of GEX. This includes not only physical items like materials, components, tools, and equipment but also intellectual property (such as drawings and specifications) and personal data. When property is lost, damaged, or otherwise found to be unsuitable for use, the owner is notified, and documented information retained.

3.8.3 Preservation

Outputs are preserved during production and service provision to ensure conformity to requirements. Preservation applies to both products and services provided by GEX. Methods of preservation include identification, handling, contamination control, packaging, storage, transmission / transportation, and protection.

3.8.4 Product release, delivery, and post-delivery

Planned arrangements for verification occur at appropriate stages to verify that the products and services meet the specified requirements. Products and services are not delivered until all planned arrangements (necessary for product preparation) have been completed. Proper documentation is retained showing the planned arrangements were followed for product release. Determining the extent of post-delivery activities is considered. Activities that occur after product delivery or service completion include actions under warranty provisions, servicing, and/or support agreements.

3.9 Nonconformance and Corrective Actions

3.9.1 Nonconformances

Ensuring that nonconforming outputs are not delivered to customers or used internally is crucial for overall product or service quality. Unaddressed non-conformities can lead to customer dissatisfaction and quality issues. A nonconformance refers to any deviation, defect, or failure to meet the specified requirements outlined in the QMS or the documented quality processes. Nonconformances can occur in any process, product, or service, and when they do occur, they are corrected as soon as possible to prevent them from happening again. Nonconformances include not meeting customer expectation, non-compliance with regulatory standards, and deviations from the documented processes (internal process requirements). Addressing nonconformances involves identification, establishing controls to prevent delivery of nonconforming outputs to customers or their unintentional use in subsequent processes, action planning depending on the impact of the output on the final product or service, and timely handling.

3.9.2 Corrective actions

Systematic steps are taken to address nonconformities, prevent their recurrence, and drive continual improvement. The corrective action process includes immediate containment actions to control and correct it and deal with the consequences, identify the root cause / comparable products or processes consideration, implement corrective action to address root cause(s) and review effectiveness. This may include updating risk and opportunity planning and any changes to the management system as appropriate. Actions taken and any concessions are documented and retained.

3.9.3 Customer complaints

Customer complaints are recorded that allege deficiencies related to the identity, quality, durability, reliability, or performance of a product and service. Upon receiving a complaint, the company reacts promptly to investigate the issue, and identify the root cause(s). Actions are taken to determine necessary corrective actions to prevent recurrence. The effectiveness of implemented actions are verified. The actions taken in response to the complaint and concessions are recorded.

4.0 PERFORMANCE EVALUATION

4.1 Overview

Performance evaluation is a critical component for maintaining the QMS and ensuring customer satisfaction. Customer satisfaction evaluation, internal audit, and management review are the primary methods to evaluate overall performance.

4.2 Customer Satisfaction

Information is monitored related to customer perception of whether their requirements have been met and serves as an indicator of the effectiveness of the QMS. It is an important indicator for business growth, reputation, and feedback for improvement. The framework involves analyzing customer requirements (understanding their needs, expectations, and preferences), establishing the methods for analysis (market research, trends analysis, CRM data, and complaint analysis), handling complaints (addressing complaints promptly and turn dissatisfied customers into positive advocates), and continuous improvement (use feedback to enhance operations, employee performance, and supplier relationships).

4.3 Internal Audit

Internal audits are conducted internally (annually) to thoroughly examine the company's processes, identify weaknesses, and assess compliance. Findings are addressed, opportunities for improvement identified, and corrective actions are implemented to ensure continual improvement.

4.4 Management Review

Management reviews are conducted internally (annually) to review QMS performance to ensure it is fit for its intended purpose, determining the need for any changes to maintain effectiveness, and to ensure the QMS aligns with the company's context and strategic direction. The key elements reviewed are the status of actions, changes in external and internal issues, adequacy of resources, and opportunities for improvement.

Appendix A is a Correlation Matrix that cross references ISO 9001:2015, Quality Manual sections, ISO 17025:2017, and NIST HB150-2:2019.

APPENDIX A

CORRELATION MATRIX

ISO 9001:2015	Quality Manual Section	ISO 17025:2017	NIST HB150-2:2019
1 Scope 4 Context of the organization 4.1 Understanding the organization and its context 4.2 Understanding the needs and expectations of interested parties 4.3 Determining the scope of the quality management system 4.4 Quality management system and its processes	1.0 Quality Management System 1.3 Scope of QMS certification 1.7.1 Organization and its Context 1.7.2 Interested Parties 1.7.3 QMS Processes	1 Scope 4 General requirements 8 Management system requirements 8.1.1 General 8.1.2 Option A 8.1.3 Option B	1 General information 1.1 Scope 3 Accreditation process Annex A – A.1 General Annex A – A.2
5 Leadership 5.1 Leadership and commitment	2.0 Quality System Management and Responsibility 2.2 Quality Duties, Responsibilities, and Authority	5 Structural requirements	5 Structural requirements
5.2 Policy 5.2.1 Establishing the Quality Policy 5.2.2 Communicating the Quality Policy	1.5 GEX Quality Policy	8.3 Control of management system documents (Option A)	3.5 Policy on scopes of accreditation of calibration laboratories B.2.4
5.3 Organizational roles, responsibilities, and authorities	2.0 Quality System Management and Responsibility 2.2 Quality Duties, Responsibilities, and Authority	4.1 Impartiality 4.2 Confidentiality	4 General requirements 4.1 Impartiality 4.2 Confidentiality
6 Planning 6.1 Actions to address risks and opportunities 6.2 Quality objectives and planning to achieve them 6.3 Planning of changes	1.6 Quality Objectives 2.3 Quality System Performance Measures 3.0 Operational Planning and Controls 3.2 Risk Management 3.3 Change Control	5.7 8.2 Management system documentation (Option A) 8.5 Actions to address risks and opportunities (Option A) 8.7.1 8.7.1 Corrective actions (Option A 8.8. Internal audits (Option A) 8.8.2	8 Management system requirements
7 Support 7.1 Resources 7.1.1 General 7.1.2 People 7.1.3 Infrastructure 7.1.4 Environment for the operation of processes 7.1.5 Monitoring and measuring resources 7.1.5.2 Measurement traceability 7.1.6 Organizational knowledge 7.2 Competence 7.3 Awareness 7.4 Communication	1.7.3 QMS Processes 1.7.4 Communication 2.4 Documented Information 3.0 Operational Planning and Controls 3.7 Measuring and Monitoring Resources 3.8 Production and Service Provision 3.8.1 Identification and Traceability	5.7 6 Resource requirements 6.1 General 6.2 Personnel 6.3 Facilities & Environmental Conditions 6.4 Equipment 6.5 Metrological traceability A.1 Annex A – General A.2 Establishing metrological traceability A.3 Demonstrating metrological traceability	6 Resource requirements 6.2 Personnel 6.3 Facilities & Environmental Conditions 6.4 Equipment Annex A – A.4 6.5 Metrological traceability
7.5 Documented information 7.5.1 General 7.5.2 Creating and updating 7.5.3 Control of documented information	2.4 Documented Information 2.4.1 QMS Documents	7.5 Technical records 7.8.8 Amendments to reports 8.2 Management system documentation (Option A) 8.3 Control of management system documents (Option A)	7.5 Technical records 8 Management system requirements

		8.4 Control of records (Option A)	
8 Operation 8.1 Operational planning and control 8.2 Requirements for products and services 8.2.1 Customer communication 8.2.2 Determination of requirements for products and services 8.2.3 Review of the requirements for products and services 8.2.4 Changes to requirements for products and services	3.0 Operational Planning and Controls 3.4 Customer communication	7 Process Requirements 7.1 Review of requests, tenders and contracts 7.8 Complaints 7.8.2 Common requirements for reports 7.8.3 Specific requirements for test reports 7.8.4 Specific requirements for calibration certificates 7.8.5 Reporting sampling – specific requirements 7.8.6 Reporting statements of conformity 7.8.7 Reporting opinions and interpretations	7 Process Requirements 7.1 Review of requests, tenders and contracts 7.7.2 PT requirements 7.8 Reporting results 7.8.2 Additional requirements for specific technical areas 7.9 Complaints Annex A – A.5
8.3 Design and development of products and services 8.3.1 General 8.3.2 Design and development planning 8.3.3. Design and development inputs 8.3.4 Design and development controls 8.3.5 Design and development outputs 8.3.6 Design and development changes	3.5 Design and Development	*No equivalent clause*	*No equivalent clause*
8.4 Control of externally provided processes, products and services 8.4.1 General 8.4.2 Type and extent of control 8.4.3 Information for external providers	3.6 Externally provided processes, products, and services	6.6 Externally provided products and services 7.2 Selection, verification and validation of methods 7.3 Sampling 7.11 Control of data and info management	6.6 Externally provided products and services 7.11 Control of data and information management Annex A – A.3 Annex A – A.4
8.5 Production and service provision 8.5.1 Control of production and service provision 8.5.2 Identification and traceability 8.5.3 Property belonging to customers or external providers 8.5.4 Preservation 8.5.5 Post-delivery activities 8.5.6 Control of changes	3.3 Change Control 3.8 Production and Service Provision 3.8.1 Identification and Traceability 3.8.2 Property Belonging to Customers or External Providers 3.8.3 Preservation 3.8.4 Product release, delivery, and post-delivery	7 Process Requirements 7.2 Selection, verification, and validation of methods 7.3 Sampling 7.4 Handling of test or calibration items 7.8.8 Amendments to reports 7.11 Control of data and info management	7 Process Requirements 7.2 Selection, verification, and validation of methods 7.3 Sampling 7.4 Handling of test or calibration items Annex A – A.4
8.6 Release of products and services	3.8.4 Product release, delivery, and post-delivery	7.8 Reporting of results 7.8.1 General	*No equivalent clause*
8.7 Control of nonconforming outputs	3.9 Nonconformance and Corrective Actions 3.9.3 Customer complaints	7.9 Complaints 7.10 Nonconforming work	7.9 Complaints 7.10 Nonconforming work
9 Performance evaluation 9.1 Monitoring, measurement, analysis and evaluation 9.1.1 General 9.1.2 Customer satisfaction 9.1.3 Analysis and evaluation	4.0 Performance Evaluation 4.2 Customer Satisfaction	7.6 Evaluation of measurement uncertainty 7.7 Ensuring the validity of results 7.8.1 Calibration measurement results 7.8.2 Additional requirements for specific technical areas 7.9 Complaints 8.9 Management reviews (Option A)	7.6 Evaluation of measurement uncertainty 7.7 Ensuring the validity of results 7.7.1 Proficiency testing 7.8 Reporting of results 7.9 Complaints 8 Mgmt. system requirements
9.2 Internal audit	4.3 Internal Audit	8.8 Internal audits (Option A)	8 Mgmt. system

			requirements
9.3 Management review 9.3.1 General 9.3.2 Management review input 9.3.3 Management review output	4.4 Management Review	8.9 Management reviews (Option A) 8.9.1, 8.9.2, 8.9.3	8 Mgmt. system requirements
10 Improvement 10.1 General 10.2 Nonconformity and corrective action 10.3 Continual Improvement	2.3 Quality System Performance Measures 4.0 Performance Evaluation 3.9 Nonconformance and Corrective Actions	7.9 Complaints 7.10 Nonconforming work 8.7 Corrective actions (Option A) 8.6 Improvement (Option A)	7.9 Complaints 7.10 Nonconforming work Annex A – A.2

REVISION HISTORY

Date	Change Description	Revision
09/20/2022	Page 8, section 4.3 Updated company address from 7330 S. Alton Way, Ste. 12-I, Centennial, CO 80112 to 4437 SW Cargo Way, Palm City, FL 34990. ECO 10093.	Q
04/12/2023	-4.4.1.1. primary functions. Added 'IT', edited 'Admin', added ' Operations'. -5.3.3 added responsibility to 'process owners and department managers' -Added 7.5.1.8 Quality System Records to include reference to DHF and PHR. -8.3.7.1 clarified validation of software language. ECO 10106	R
03/07/2024	-Restructure of the Quality Manual sections. General review and update to simplify. -Changed the Quality Policy from, "GEX staff and management are committed to the continual improvement of the QM, meeting Quality Objectives, and provision of products and services designed to fulfill customer requirements" to ""Deliver solutions that fulfill customer requirements and exceed customer expectations with a commitment to continuous improvement and meeting quality objectives." -Appendix A removed reference to ISO 9001:2008 and replaced with Quality Manual section, ISO 17025:2017 and NIST HB150-2:2019. -2.2 Added reference to the BCP. ECO 10128	S

APPROVED

By Dominique Taylor at 9:42 am, Mar 07, 2024