GEX Corporation

QUALITY SYSTEM MANUAL

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SCOPE - SECTION 1

1.1 Quality Policy

GEX QUALITY POLICY STATEMENT

GEX staff and management are committed to the continual improvement of all quality processes to provide products and services designed to fulfill customer requirements.

President: _____ Date: _____

1.2 Introduction

GEX is the world leader in providing total DOSIMETRY SOLUTIONS for industrial users. We continuously work with radiation equipment systems manufacturers, in-house users and contract irradiation facilities around the world to develop complete dosimeter systems designed to meet end user requirements.

GEX is located in Centennial, Colorado

GEX Corporation
7330 S. Alton Way, Suite 12-I
Centennial, CO 80112 USA

With the implementation of the Quality System, GEX has embraced continuous improvement through Defect Prevention and Defect Detection.

The purpose of this manual is to define and describe the quality system, to define authorities and responsibilities of the management personnel affected by the system, and to provide general procedures for all activities comprising the quality system. This manual specifies the quality system policies used by GEX to provide the highest degree of Quality throughout all phases of the product life cycle - from design through servicing. The GEX Quality System was developed to provide the means of satisfying applicable requirements defined in ISO 9001:2008.

This Quality Manual is reviewed annually by Senior Management to ensure that it remains current. Ensuring that changes to the Manual are properly approved, instituted and implemented shall be the responsibility of the Management Representative. The Quality Assurance/Regulatory representative shall ensure that changes to the Quality System are properly executed.

President: _____ Date: _____

Management Representative: _____ Date: _____

1.3 Application

The quality management system defined in this manual applies to the design, manufacture and distribution of all Dosimetry Products and Services offered by GEX Corporation.

1.4 Scope

Products and Services for industrial radiation processing dosimetry

REFERENCE DOCUMENTS - SECTION 2

2.1 Standards and Guidelines

- ISO 9001:2008: Quality Management Systems – Requirements
- ISO 9000:2005 QMS – Fundamentals and vocabulary
- ISO 9004:2000 QMS – Guidelines for performance improvements
- ISO 17025:2005 QMS – General requirements for the competence of testing and calibration laboratories
- NIST Handbook 150 – NVLAP Procedures and General Requirements

TERMS AND DEFINITIONS - SECTION 3

3.1 The terms and descriptions used in this Manual are generally defined within ISO 9001 or are otherwise explained in this document. In addition, the Laboratory Department embraces and has procedures with information and instructions to provide specific conformance with ISO 17025 and NIST Handbook 150 requirements.

QUALITY MANAGEMENT SYSTEM - SECTION 4

4.1 GENERAL REQUIREMENTS

The Executive Management is ultimately responsible for establishing, implementing, and maintaining the quality system. Specific responsibilities are comprised of: formulating the quality policy; defining the organizational structure; assigning authorities and responsibilities; appointing the management representative; periodically reviewing the quality system; and making available the resources and personnel necessary to maintain the system.

Additionally, Executive Management ensures that the company avoids derogatory or questionable activities that would diminish confidence in its competence, impartiality, judgment, or operational integrity.

4.1.1 Process Approach

The quality management system is designed as a system of interrelated processes. All main activities in the company are defined as Quality System Processes and are grouped into the following six categories:

- Customer Requirements,
- Product Realization,
- Measurement, Analysis and Improvement,
- Management Responsibility,
- Resource Management
- Continual Improvement

4.1.1.1 The sequence and interrelation between the six groups and individual processes are illustrated in the Quality System Processes Diagram (see Appendix A). This documentation defines the quality system processes and their sequence and interaction.

4.1.1.2 Each process is further defined in the Quality System Processes Table (see Appendix C). The definition of the processes and their sub-processes are documented in this table and in associated Quality System Procedures and Work Instructions.

4.1.1.3 A listing of areas where Quality is applied is listed in Appendix B. This listing segregates areas of the company along functional lines and is used as the basis for job descriptions.

4.1.1.4 A listing of the Company's documented procedures is provided in the Document Control Master List maintained by the QA Manager. These Quality System documents define criteria and methods needed to ensure that the operation and control of quality system processes are effective. This includes assignment of responsibilities and allocation of resources for the process, instructions on how to carry out (or operate) the process, and definition of methods for monitoring and/or measuring the effectiveness of the process.

4.1.2 Resources and information

4.1.2.1 Quality Assurance is responsible for determining resource and information requirements necessary to support the operation, the monitoring of quality system processes, and for communicating these requirements to the Senior Management. The Senior Management is responsible for ensuring the availability of necessary resources and information. *Section 6.1 Provision of Resources* explains in more detail how resource requirements are identified and satisfied.

4.1.3 Monitoring and measurement

4.1.3.1 Performance of quality system processes is systematically monitored and measured. This is to ensure their effectiveness and identify opportunities for improvement.

4.1.3.2 Performance of quality system processes are monitored through internal quality audits. The overall performance of the quality system is monitored by measuring customer satisfaction.

4.1.3.3 Quality system processes are reviewed and analyzed by the management review of the quality system (refer to *Section 5.6*).

4.1.4 Continual improvement

4.1.4.1 Quality management system processes are regularly reviewed by the Senior Management to identify any possible failures or breakdowns. Actions necessary to address actual or potential problems and to maintain the effectiveness of these processes are implemented through corrective and preventive actions and through quality objectives.

4.1.4.2 Quality Manual Section 8.5 and Quality System Procedure QSP-56-01, Management Review, define how the quality management system itself ensures its own compliance and effectiveness.

4.1.5 Subcontracted processes

4.1.5.1 When processes that affect product conformity are outsourced, special controls are implemented to ensure that these processes meet specified requirements. Such controls may include, as appropriate:

- Evaluation and pre-qualification of suppliers
- Assessment of subcontractor's manufacturing processes and their quality system
- Flow-down of customer (contract) requirements
- Monitoring of supplier quality performance
- Requirements for process control, inspection, testing or other records demonstrating product conformity
- Verification of the supplied product

4.1.5.2 Ensuring control over outsourced processes does not absolve GEX Corporation of the responsibility to conform to all customer requirements.

4.2 DOCUMENTATION AND RECORDS

This section defines the scope of the quality system related documentation.

4.2.1 Documentation

- **Quality Manual (MAN-01-01):** This top-level document defines the company's quality policies and quality objectives; defines the scope of the quality system, including details and justification for any exclusion (refer to Section 1.4); describes the overall quality system, its processes, and their sequence and interaction; and references applicable Quality System Procedures.
- **Quality System Procedures (QSP):** These are second-level documents defining specific quality system processes. Quality System Procedures explain the what, when, who and how for a process, and

define what records must be established to document the results. Quality System Procedures are code numbered QSP-SS-NN. QSP stands for Quality System Procedure, SS is the section in the quality system to which the procedure pertains, and NN is the consecutive number of a procedure for the section.

- **Quality Forms (QF):** These are usually one-page forms or matrices defining a "template" for establishing a record. When issued as independent documents the forms are code numbered QF-SS-NN. QF stands for Quality Form, SS is the section in the quality system to which the procedure pertains, and NN is a consecutively assigned number of a form for the section.
- **Work Instructions (WI):** The purpose of work instructions is to guide personnel in performing specific tasks, such as carrying out and controlling production processes, handling products, calibrating measuring equipment, conducting tests or inspections, etc. When issued as independent documents the instruction is code numbered WI-SS-NN. WI stands for Work Instruction, SS is the section in the quality system to which the procedure pertains, and NN is a consecutively assigned number of a form for the section.
- **Specifications (SPEC):** These documents include specifications related to components, subassembly, assembly, and packaging, as well as bills of materials, software specifications, and process flow charts, specifications for equipment calibration and maintenance, and specifications for inspection processes. More descriptive detail of these documents is provided in QSP-42-01, Control of Documents.
- **Customer Communications**: These documents include manuals, product information sheets, technical documents or memoranda, or any other document that GEX determines to be important in communicating product and service information to end users.
- **Standards and codes:** These are international, national and local regulations, standards, and codes that define operational, quality and product requirements.

MANAGEMENT RESPONSIBILITY - SECTION 5

5.1 MANAGEMENT COMMITMENT

5.1.1 Senior Management is committed to communicating the importance of meeting customer, as well as statutory and regulatory requirements. The Management Representative is responsible for implementing this commitment by promoting awareness of customer requirements throughout the organization.

5.1.2 Senior Management periodically reviews the quality management system to ensure its continuing suitability, adequacy, and effectiveness.

5.1.3 Senior Management is committed to providing the resources necessary for establishing, implementing, and improving the quality management system.

5.1.4 Quality Assurance and all Laboratory staff are responsible for ensuring compliance with NIST Handbook 150.

5.2 CUSTOMER FOCUS

5.2.1 The principal objective of the quality management system is to focus our organization on the customer, and in particular, on customer satisfaction. The key to achieving high customer satisfaction is an accurate determination of customer requirements and an effective verification that the requirements are met.

5.3 QUALITY POLICY

5.3.1 Quality policy is documented in this manual in *Section 1.1 Quality Policy*.

5.3.2 Quality policy is established by the President. In formulating the quality policy, the President ensures that the policy is appropriate to the purpose of the company, and includes a commitment to comply with the requirements and continually improve the effectiveness of the quality management system.

5.3.3 Quality policy is posted at the company facility, and its role is explained and discussed at the general orientation training provided to all employees.

5.4 QUALITY SYSTEM PLANNING

5.4.1 Quality objectives

5.4.1.1 Quality objectives are established during Management Review to implement the quality policy, to meet requirements for products and processes, and to improve quality system and quality performance.

5.4.2 Quality system planning

5.4.2.1 Quality system processes are planned to ensure that the system is appropriate for its intended purpose, and that it is effective and efficient. The purpose of the quality system is to:

- Achieve the quality policy;
- Ensure and demonstrate our ability to provide products and related services that consistently meet customer requirements and applicable regulatory requirements;
- Ensure a high level of customer satisfaction; and
- To facilitate continual improvement

5.5 ORGANIZATION

5.5.1 Responsibility and authority

5.5.1.1 An Organizational Chart is provided in an addendum to this manual with control number MAN-ADD-01.

5.5.1.2 All departments and functions in the company are responsible for implementing, maintaining, and improving the quality system.

5.5.1.3 For the purpose of administrating the quality management system, Senior Management includes the President, QA Manager, and Production Manager.

5.5.1.4 The Laboratory Manager and all applicable Laboratory staff are responsible for administering the NIST Handbook 150 requirements within the Laboratory Department.

5.5.2 Management Representative

5.5.2.1 GEX Corporation appoints as the Management Representative the Quality Assurance Manager. Management Representative has the authority and responsibility to:

- Ensure that the quality management system is implemented, maintained and continually improved;
- Promote awareness of regulatory and customer requirements throughout the organization;
- Report to the Senior Management on the efficiency and performance of the quality system, and
- Coordinate communication with external parties on matters relating to the quality system and ISO 9001:2008 registration.

5.5.3 Internal communication

5.5.3.1 Internal communication regarding the quality system flows two ways:

- The management communicates to the organization the quality policy and objectives; customer and regulatory requirements; product and process specifications; verification and validation requirements; and instructions on how to implement and use the quality system.
- The organization communicates to the management information and data regarding quality performance, the effectiveness of the quality system, customer satisfaction, and opportunities for improvement.

5.5.3.2 The information is communicated through:

- Paper or electronic documents, such as manuals, procedures, instructions, drawings, specifications, quality records, reports, etc.
- E-mails, memos, and meetings
- Training and awareness programs
- Employee suggestions, surveys and feedback

5.6 MANAGEMENT REVIEW

5.6.1 General

5.6.1.1 Management reviews of the quality management system are conducted at least once a year. More frequent reviews are scheduled in periods when organizational, technological, product, or other changes require increased attention and input from the Senior Management.

5.6.1.2 The purpose of management reviews is to:

- Evaluate the suitability, adequacy and effectiveness of the quality system;
- Consider changes to the quality management system and to the quality policy and quality objectives; and
- Identify opportunities for improvement of the quality system, processes and products.

5.6.1.3 Management reviews are chaired by the President and are attended by managers representing: R&D, Admin., Marketing/Sales, Operations/Production, and Quality Assurance

5.6.2 Review input

5.6.2.1 Input into the management reviews consists of information and data related to quality performance of the organization. At a minimum, this includes:

- Results of audits,
- Customer feedback and complaints,
- Process performance and product conformity data,
- Status of preventive and corrective actions,
- Status of quality objectives,
- Changes that could affect the quality system,
- New or revised regulatory requirements,
- Follow-up actions from earlier management reviews, and
- Recommendations for improvement.

5.6.3 Review output

5.6.3.1 Management reviews are concluded with setting new quality objectives and initiating actions to improve the quality management system, processes, and products.

5.6.3.2 Results of management reviews are documented in minutes of the review meeting. The minutes include improvement actions, and assign responsibilities and allocate resources for implementation of these actions.

RESOURCE MANAGEMENT - SECTION 6

6.1 PROVISION OF RESOURCES

6.1.1 Resources required for implementing, maintaining and improving the quality management system, and for addressing customer satisfaction, include personnel, infrastructure, work environment, process equipment, materials, information, and financial resources.

6.1.2 Determination of resource needs for specific activities is integrated with the process of defining and initiating the activity. It may take the form of personnel assignments, allocation of space or equipment, training, procurement decisions, budgets, etc.

6.1.3 Depending on the type and nature of the operation or activity, resource requirements are defined in:

- Quality manual, Quality System Procedures and work instructions
- Product specifications and production plans
- Job descriptions and training programs
- Minutes of management reviews, quality objective records, and corrective and preventive action requests

6.1.4 Senior management has the responsibility and authority for provision of resources.

6.1.5 Management reviews of the quality system are the principal forum for determining resource requirements and providing resources for maintaining and improving the quality system, and for enhancing customer satisfaction.

6.2 HUMAN RESOURCES coordinated by the Admin Dept.

6.2.1 General

6.2.1.1 Personnel performing work affecting product quality are competent. Competence is determined on the basis of appropriate education, training, skills and experience.

6.2.1.2 Admin and the Quality departments are responsible for training and awareness programs for company-wide participation, such as: general orientation, rules and regulations, quality system, safety, and other company-wide systems and issues.

6.2.1.3 Departmental managers are responsible for identifying competency requirements and for providing training in their departments. Departmental training is primarily focused on increasing the level of skills in operating equipment and processes, conducting inspections and testing, and skills as appropriate for particular positions and jobs.

6.3 INFRASTRUCTURE

6.3.1 Buildings, workspace and associated utilities

6.3.1.1 Infrastructure and facilities, such as buildings, workspaces and associated utilities, etc., are appropriate and are properly maintained to achieve conformity to product requirements.

6.3.1.2 Departmental managers are responsible for identifying the need and requirements for new, and/or modification or repair of existing infrastructure and facilities in their departments.

6.3.1.3 Maintenance of buildings and facilities may be performed by external contractors. This includes regularly scheduled maintenance of lighting systems, air conditioning and heating systems, landscaping, and cleaning.

6.3.2 Process equipment

6.3.2.1 Procurement of new, and/or modification of existing process equipment (including hardware and software) are planned in conjunction with development of manufacturing processes.

6.3.3 Supporting services

6.3.3.1 Supporting services required by GEX Corporation include transportation, communication, and IT services:

- Transportation services are purchased from parcel delivery and courier services, and from trucking or other transportation companies or consolidators, as required.
- Communication services are provided by various telephone, wireless, and internet access companies. Admin is responsible for administrating and coordinating these contracts.
- IT systems are designed and implemented by external consultants, while the day-to-day operating of the systems is the responsibility of the Quality Manager who serves as the 'IT Manager' and is responsible for selecting IT consultants and for administrating IT contracts.

6.3.4 Equipment Maintenance

6.3.4.1 Key process equipment, machines, hardware, and software are regularly maintained in accordance with maintenance plans specified by equipment manufacturers or the Technical Services Manager responsible for the equipment.

6.4 WORK ENVIRONMENT

6.4.1 Human factors

6.4.1.1 Admin and departmental managers are responsible for ensuring suitable

physical, social and psychological conditions in the workplace. This is to include such aspects as temperature, lighting, and cleanliness.

6.4.1.2 Production and Quality Assurance are responsible for identifying those operations where extreme environmental conditions could affect quality performance of personnel and result in product nonconformities. Where appropriate, limits of exposure and/or mitigating measures are defined and implemented for these operations.

6.4.1.3 Health and safety management system is independent from the quality management system. It is administrated by Admin.

6.4.2 Work environment in production and storage areas

6.4.2.1 Work environment is properly controlled in areas where environmental conditions could have an adverse effect on product quality.

PRODUCT REALIZATION - SECTION 7

7.1 PLANNING OF PRODUCT REALIZATION

7.1.1 Production and quality planning (design transfer)

7.1.1.1 Production processes and product verification activities are planned in accordance with Design Control procedures.

7.2 CUSTOMER-RELATED PROCESSES

7.2.1 Determination and Review of requirements related to the product

7.2.1.1 Product requirements are determined, to include:

- Requirements specified by the customer
- Requirements not stated by the customer, but necessary for intended use

7.2.1.2 Prior to the commitment to supply a product to the customer, orders are reviewed to ensure that:

- Product requirements are defined;
- Any ambiguities and conflicts in contract or order requirements are resolved; and
- GEX is able to meet customer requirements.

Records of the results of the review and any associated actions are maintained.

7.2.1.3 Change orders and amendments are received and reviewed following the same procedure that applies to initial orders. Change orders are communicated to all functions within the organization that may be affected by the change of customer requirements.

7.2.2 Customer communication

7.2.2.1 The Marketing department is responsible for developing and controlling the company's brochures, catalogs, internet site and other forms of promotional and product information material. These materials are based on technical specifications developed by R&D. Only designated personnel from Marketing, Sales, Customer Service and R&D are authorized to communicate with customers regarding product information.

7.3 DESIGN AND DEVELOPMENT

7.3.1 General

7.3.1.1 GEX designs its own standard catalog products as well as customer-specified products and modifications. R&D is responsible for design.

7.3.2 Design planning

7.3.2.1 R&D is responsible for the planning of design projects, including the identification of design, review, verification and validation activities; scheduling the project; assignment of qualified personnel; and control of organizational and technical interfaces.

7.3.3 Design inputs

7.3.3.1 Design input requirements are developed by R&D from product concepts, such as product briefs, sketches, models, rough prototypes, etc. Design inputs are reviewed and approved before their release to the design team.

7.3.4 Design outputs

7.3.4.1 Product design outputs consist of documents, samples, models, math data, software, etc., which specify the product and its manufacturing, packaging, labeling, installation and servicing; as well as product acceptance criteria.

7.3.5 Design reviews

7.3.5.1 Design reviews are carried out at appropriate stages in accordance with the design project plan. The purpose of the design reviews is to evaluate the ability of the design to meet design input requirements, and to identify any problems and propose necessary actions.

7.3.5.2 Participants in design reviews include representatives of functions concerned with the design stage being reviewed, as well as other specialist personnel.

7.3.6 Design verification and validation

7.3.6.1 Product designs are verified and validated in accordance with planned

arrangements (design project plan) to ensure that the design outputs have met the design input requirements, and that the resulting product is capable of meeting the requirements for specified application or intended use.

7.3.6.2 Records of the results of design verification and validation, and any necessary actions, are maintained.

7.3.7 Design changes

7.3.7.1 Design changes are reviewed, verified and validated as appropriate, and approved before implementation.

7.4 PURCHASING

7.4.1 Supplier evaluation and monitoring

7.4.1.1 GEX evaluates its suppliers and purchases only from those who can satisfy quality requirements. Quality Assurance and Purchasing monitor supplier quality performance.

7.4.2 Purchasing information

7.4.2.1 Purchasing documents are prepared by Admin. The documents clearly and completely describe ordered products, including precise product identification and quality requirements. Purchasing documents are reviewed and approved prior to release.

7.4.3 Verification of purchased product

7.4.3.1 Purchased products are verified prior to use in production and/or dispatch to customers whenever necessary. Appropriate methods for purchased product verification and acceptance are determined as part of design control or by the Quality Manager, as necessary.

7.5 PRODUCTION AND SERVICE PROVISION

7.5.1 Control of production and service provision

7.5.1.1 General requirements

Product Manufacturing and provision of associated services are carried out under controlled conditions. The controlled conditions include the control of, as applicable:

- Product and process information and work instructions
- Process equipment
- Monitoring and measuring equipment
- Monitoring and measurement activities

- Product release and delivery
- Labeling and packaging

7.5.2 Validation of processes for production and service provision

7.5.2.1 Special processes are those processes where the resulting output cannot be verified by subsequent measurement or monitoring. Production and Quality Assurance are responsible for identifying, validating and documenting special processes.

7.5.3 Identification and traceability

7.5.3.1 **Identification:** Materials, components and finished products are identified throughout all stages of product realization and when in storage.

7.5.3.2 **Traceability:** Traceability is based on identifying the finished products with unique control numbers. Traceability is maintained when specified internally to facilitate corrective actions.

7.5.4 Preservation of product

7.5.4.1 **Handling and preservation:** Production is responsible for ensuring that containers holding products are suitable and are in good condition, that equipment used for internal transportation of products is well maintained and is properly operated, and that products are adequately protected during production and storage.

7.5.4.2 **Storage:** Stockrooms and storage, staging, and holding areas are controlled by the department that brings in new stock or uses the area. Storage areas are appropriate to ensure adequate preservation and protection of product. Procedures and/or work instructions are established for control of product with limited shelf life or requiring special storage conditions.

7.5.4.3 **Packaging, labeling and shipping:** Production is responsible for these operations. Finished goods are packaged by trained employees and the contents are readily identifiable.

7.6 CONTROL OF MONITORING AND MEASURING EQUIPMENT

7.6.1 General

7.6.1.1 Appropriate measuring and monitoring equipment is selected and maintained to ensure that measurements are accurate and consistent with the measurement requirements. Equipment used for ensuring and verifying product conformity is calibrated.

7.6.2 Measuring and monitoring equipment calibration and maintenance

7.6.2.1 The scope of the calibration control system extends to the measuring and

test equipment, comparative reference hardware (such as gauges and templates), and test software used for:

- Setup and monitoring of production processes
- Monitoring of environmental conditions
- Verification of product conformity
- Operations where defined accuracy of a measurement is required to assure product conformity

7.6.2.2 Technical Services is responsible for calibrating and maintaining measuring and monitoring equipment. All active equipment is inventoried in a controlled list, indicating their calibration status and location.

7.6.2.3 Measuring equipment is checked, adjusted and re-adjusted as necessary; and calibrated at specified intervals (or prior to use) against measurement standards traceable to international or national measurement standards.

7.6.2.4 Calibration results are recorded in a calibration certificate and the calibrated equipment is labeled with a calibration sticker to identify the calibration status.

7.6.2.5 Measuring and monitoring equipment is safeguarded from adjustments that would invalidate the measurement result.

7.6.2.6 Measuring and monitoring equipment is protected from damage and deterioration during handling, maintenance and storage.

7.6.3 Validity of measurements made with nonconforming equipment

7.6.3.1 When measuring equipment is found not to conform to requirements, previous measuring results are reassessed, and appropriate action is taken on the equipment and any product affected.

7.6.4 Validation of software

7.6.4.1 In-house developed inspection, test, and monitoring software is validated before it is used for product assurance or verification. Commercial software is purchased with validation certificates where available. Software is revalidated or recertified when conditions for which it was initially validated are materially changed.

MEASUREMENT, ANALYSIS AND IMPROVEMENT - SECTION 8

8.1 GENERAL

8.1.1 Planning

8.1.1.1 Measurement and monitoring activities to ensure and verify product conformity are defined.

8.1.1.2 The conformity and effectiveness of the quality system are monitored by internal audits and by measuring quality performance and customer satisfaction. Results of these activities are reported to the senior management and are used to identify opportunities for improvement.

8.1.2 Statistical techniques

8.1.2.1 As applicable, statistical techniques may be applied to the following types of activities:

- Testing and validation of designs
- Set up of process equipment
- Testing and validation of processes
- Establishment of plans for inspections and testing
- Evaluation of measurement systems
- Analysis of quality performance and other company-level data

8.1.2.2 Departmental managers are responsible for identifying the need for using statistical techniques in their departments and in other activities for which they are responsible. Quality Assurance may be called upon to assist other departments in selecting and documenting specific techniques.

8.1.3 Sampling plans

8.1.3.1 Sampling plans for inspections, testing and other product and process acceptance activities are documented. Sampling plans are reviewed and approved by Quality Assurance to ensure that they are based on valid statistical rationale and are appropriate. They are either included with the inspection/testing instructions to which they pertain, or are issued as independent documents.

8.1.3.2 Sampling plans are reviewed and re-evaluated whenever there is a significant change in reject rates (identified nonconformities) at a given inspection point, and when a nonconforming product is shipped, or otherwise identified after it has passed its acceptance inspection.

8.2 MONITORING AND MEASUREMENT

8.2.1 Post-production feedback and customer satisfaction

8.2.1.1 The post-production feedback system provides early warning of quality problems and input into the corrective and preventive action processes. Information and data pertaining to customer satisfaction are collected from several sources, including:

- Customer complaints and other feedback
- Customer satisfaction surveys
- Product returns

8.2.1.2 Marketing is responsible for developing suitable indicators of customer satisfaction, and for defining methods for collecting and analyzing the pertinent information.

8.2.2 Internal audit

8.2.2.1 Quality Assurance is responsible for conducting internal audits of the quality management system to determine whether the quality system:

- Conforms to quality plans, to management system requirements as defined in this quality manual and Quality System Procedures, and
- Is effectively implemented and maintained.

8.2.2.2 Internal audits are conducted in accordance with a planned program, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of the previous audits.

8.2.2.3 Appropriate corrective actions are taken by management personnel responsible for the areas where nonconforming processes and/or practices are identified by the audit. Auditors follow up to ensure that the actions taken are fully implemented and are effective.

8.2.3 Monitoring and measurement of processes

8.2.3.1 Quality management system processes are monitored by a variety of approaches and techniques, as appropriate for a particular process and its importance. These include:

- Conducting internal audits of the quality system
- Conducting Management Review meetings
- Evaluating corrective and preventive action effectiveness
- Measuring and monitoring customer satisfaction

8.2.4 Monitoring and measurement of product

8.2.4.1 The monitoring and measurement program for products is defined in specifications, production work orders, purchasing documents, and in inspection and testing procedures and include:

- Verification of purchased product
- In-process inspections.
- Final acceptance inspection

8.2.4.2 Results of inspections and tests are recorded.

8.2.4.3 Products are released for distribution only after all specified activities have been satisfactorily completed and conformity of the product has been verified. Only personnel performing final product inspections and tests

have the authority to release products. The identity of the person authorizing product release is recorded.

8.3 CONTROL OF NONCONFORMING PRODUCT

8.3.1 Identification, documentation, review and disposition

8.3.1.1 Nonconforming products are documented in a Product Nonconformity Report (PNR). The report describes the nonconformity, documents the disposition decision, and records closeout of follow-up activities. Quality Assurance is responsible for reviewing nonconformities and deciding on the disposition of nonconforming products

8.3.1.2 When nonconforming product is detected after delivery or use has started, the effects, or potential effects of the nonconformity are evaluated by Quality Assurance, and appropriate action is taken.

8.4 ANALYSIS OF DATA

8.4.1 General

8.4.1.1 Quality Assurance coordinates the collection and analysis of appropriate data to demonstrate the suitability and effectiveness of the quality management system, and to identify opportunities for improvement.

8.4.2 Scope

8.4.2.1 The quality performance data focuses on providing information relating to:

- Customer feedback,
- Conformity to product requirements,
- Characteristics of processes and products, and
- Supplier quality performance

8.5 IMPROVEMENT

8.5.1 Continual improvement

8.5.1.1 GEX continually improves the effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions, and management review.

8.5.1.2 Internal audit results and quality performance data are analyzed by management review to assess the effectiveness of the quality system and current organizational performance. Opportunities and priorities for improvement are identified by comparing present quality performance to goals and aspirations defined in the quality policy.

8.5.2 Customer complaints

8.5.2.1 Customer complaints that allege deficiencies related to the identity, quality, durability, reliability, or performance of a distributed product are logged and the results of the investigation are documented.

8.5.3 Corrective and preventive action

8.5.3.1 Corrective actions are taken to eliminate causes of actual nonconformities in order to prevent their recurrence.

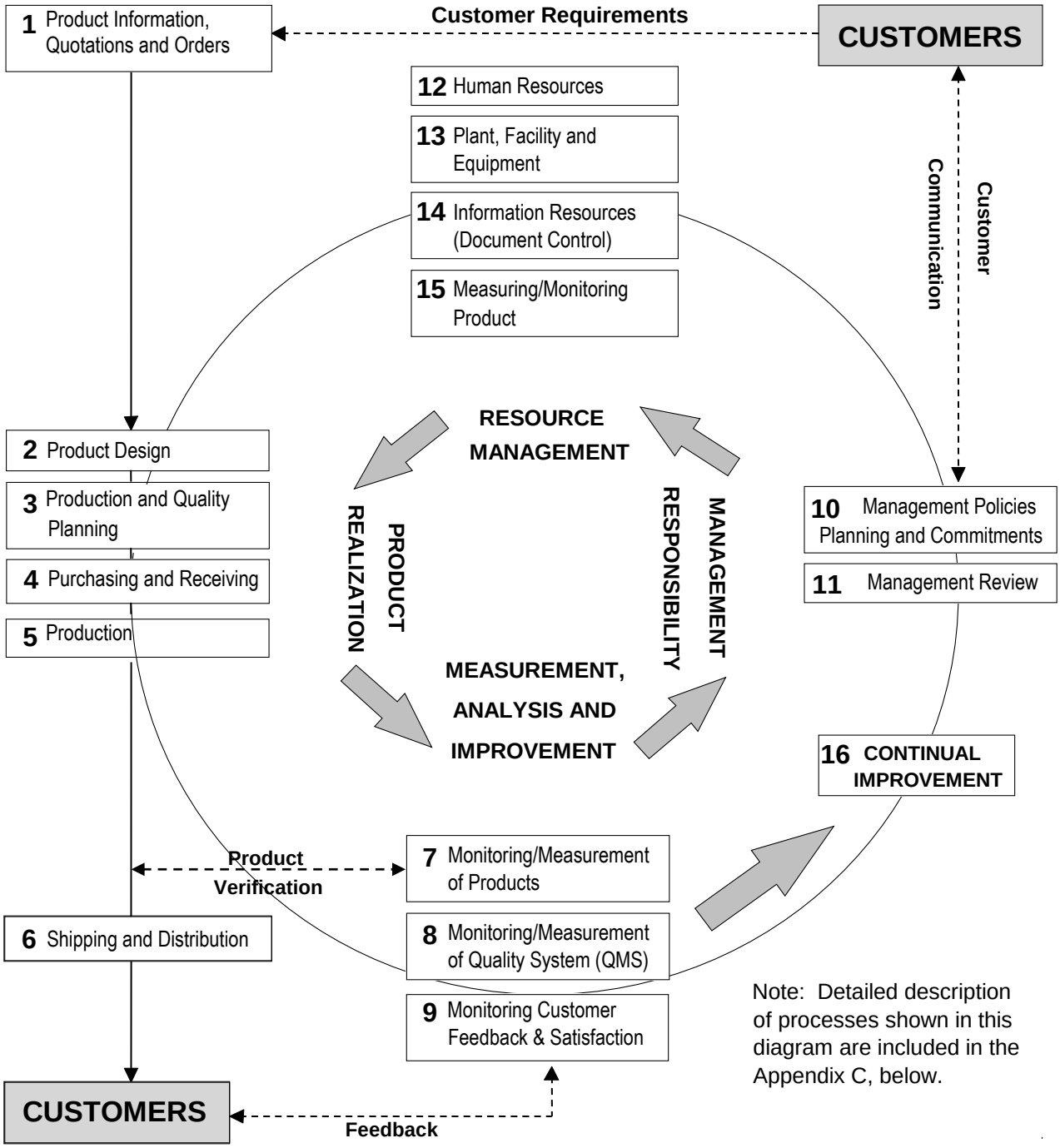
8.5.3.2 Preventive actions are implemented to eliminate causes of potential nonconformities in order to prevent their occurrence.

8.5.3.3 The process for taking corrective and preventive actions includes requirements for:

- Reviewing nonconformities and potential nonconformities
- Determining causes for actual and potential nonconformities
- Evaluating the need for action to ensure that nonconformities do not recur and that potential nonconformities are prevented
- Determining and implementing actions needed
- Recording the results of any investigations and of actions taken
- Reviewing the corrective or preventive action taken and its effectiveness

APPENDIX A

QUALITY SYSTEM PROCESSES DIAGRAM



Note: Detailed description of processes shown in this diagram are included in the Appendix C, below.

APPENDIX B

QUALITY AREAS BY FUNCTION

Brief definitions of each area provide the basis for understanding the company structure and for assigning responsibilities in the form of job descriptions, based around these primary functions:

Management – Company sales strategy, resourcing, financing, quality and technology planning.

Sales – Sales and marketing of the company's products and services including marketing communications, website design, sales efforts, promotion and OEM alignment.

Admin – Administrative responsibilities of the company including daily office tasks, bookkeeping, human resources, supplier and customer account maintenance, and order processing.

Customer Service – Customer assistance with technical and functional issues beginning with order placement and including product usage communications, facilitation of company services to customers, software support and education.

R & D – Research and Development for the company based on internal and external driving forces.

Purchasing – Purchasing and vendor relations function.

Receiving – Incoming shipment receipt and verification function.

Warehouse – Materials and product storage and inventory function.

Production – Manufacturing and packaging function.

Shipping – Shipping functions including packaging of goods for final shipment, execution of shipments, and monitoring of shipment tracking.

Technical Services – Including equipment calibration and maintenance, management of measurement operations, IT maintenance and support, and facility maintenance operations.

Laboratory – Dosimeter Measurement Services.

Quality Assurance – Management and oversight of all Quality operations.

APPENDIX C

QUALITY SYSTEM PROCESSES TABLE

1 PRODUCT INFORMATION, QUOTATIONS AND ORDERS	
Purpose	To provide customers with product information, determine customer requirements, prepare bids and quotations, submit tenders, and take orders from, or enter into contracts with, customers.
Process Owners	Sales, Customer Service
Sub-Processes and Procedures	• Providing product information - QSP-72-01 • Determining product requirements - QSP-72-01, QSP-72-02 • Determining customer requirements - QSP-72-01, QSP-72-02 • Evaluating capability and capacity to meet requirements - QSP-72-01, QSP-72-02 • Preparing quotations, bids and tenders - QSP-72-01 • Entering orders (or signing contracts) - QSP-72-01 • Receiving, entering and processing change orders - QSP-72-01
Audit Areas	Sales, Customer Service, Admin, QA, Management
Audit ISO 9001	7.2 Customer-related processes

2 PRODUCT DESIGN	
Purpose	To design products meeting the design input requirements.
Process Owners	R&D, QA
Sub-Processes and Procedures	• Planning and scheduling design projects - QSP-73-01 • Reviewing and controlling design input - QSP-73-01 • Conducting design reviews - QSP-73-01 • Establishing design output documents - QSP-73-01, QSP-42-01 • Verifying and validating product designs - QSP-73-01 • Controlling design changes - QSP-73-01, QSP 73-02
Audit Areas	R&D, QA, Sales, Management
Audit ISO 9001	7.3 Design Control

3 PRODUCTION AND QUALITY PLANNING	
Purpose	To plan and develop processes needed for manufacturing and verification of product.
Process Owners	R&D, Production, Management, QA
Sub-Processes and Procedures	• Determining requirements for products - QSP-72-01, QSP-72-02, QSP-73-01 • Developing, verifying and documenting production processes (process flowcharts, process sheets, equipment setup instructions, tooling specifications, operator instructions, etc.) - QSP-71-01, QSP-75-01 • Establishing product acceptance criteria and product verification requirements (measuring, inspections, tests, etc) - QSP-64-01, QSP-71-01, QSP-73-01, QSP-74-03, QSP-76-01, QSP-82-03, QSP-82-04
Audit Areas	R&D, Production, Management, Technical Services, QA
Audit ISO 9001	7.1 Planning of product realization 8.1 Measurement, analysis and improvement - General

4 PURCHASING AND RECEIVING	
Purpose	To select qualified vendors and to purchase from them materials, components, and services necessary for the manufacture and delivery of the product.
Process Owners	Purchasing, Admin
Sub-Processes and Procedures	• Evaluating and selecting suppliers and subcontractors - QSP-74-01 • Maintaining a list of approved suppliers - QSP-74-01 • Preparing, reviewing and issuing purchasing documents - QSP-74-02 • Receiving purchased products - QSP-74-03 • Inspecting or otherwise verifying conformity of purchased products - QSP-74-03 • Applying and recording purchased product identification and traceability - QSP-75-01, QSP-75-05 • Monitoring quality performance of suppliers - QSP-74-01 • Communicating with suppliers regarding their quality performance (notifications, requests for corrective actions, etc.) - QSP-74-01, QSP-85-04
Audit Areas	Purchasing, QA, Receiving, Warehouse, Admin
Audit ISO 9001	7.4 Purchasing

5 PRODUCTION	
Purpose	To manufacture products conforming to requirements, and to install the products.
Process Owners	Production
Sub-Processes and Procedures	• Training process operators and technicians (on-the-job) - QSP-62-01 • Validating and controlling manufacturing processes - QSP-75-01, QSP-75-03 • Maintaining production work environment - QSP-64-01 • Carrying out manufacturing processes - QSP-75-01 • Maintaining and recording product identification and traceability - QSP-75-05 • Performing product labeling and packaging operations - QSP-75-06, QSP-82-04 • Managing and operating storage areas and warehouses - QSP-75-05, QSP-75-07 • Maintaining production equipment and tooling - QSP-63-01, QSP-76-01
Audit Areas	Production, Packaging, Warehouse, QA, Technical Services
Audit ISO 9001	7.5 Production and service provision

6 PACKAGING AND SHIPPING	
Purpose	To deliver product to customers and distributors.
Process Owners	Production, Shipping
Sub-Processes and Procedures	• Packaging and shipping - QSP-75-06, QSP-75-07 • Certification of Product - QSP-75-07 • Establishing and maintaining shipping and distribution records - QSP-42-03, QSP-75-07
Audit Areas	Production, Shipping, Sales, Warehouse, Admin, QA
Audit ISO 9001	7.5 Production and service provision

7 MONITORING AND MEASUREMENT OF PRODUCT	
Purpose	To verify product conformance.
Process Owners	QA, Production
Sub-Processes and Procedures	• Verification of purchased product - QSP-74-02 • Monitoring, measuring, and testing products - QSP-74-03, QSP-81-02, QSP-82-03, QSP-82-04 • Identifying and controlling nonconforming products - QSP-83-01 • Applying and maintaining inspection status identification - QSP-74-03, QSP-75-05, QSP-82-03, QSP-82-04, QSP-83-01 • Releasing products - QSP-82-04
Audit Areas	Production, Receiving, Purchasing, , QA, Technical Services
Audit ISO 9001	8.2.4 Monitoring and measurement of product 8.3 Control of nonconforming product

8 MONITORING AND MEASUREMENT OF QMS	
Purpose	To verify conformity of the quality management system, and to evaluate its effectiveness and efficiency.
Process Owners	Management, QA
Sub-Processes and Procedures	• Conducting internal audits of the quality system - QSP-82-02 • Analyzing and evaluating results of internal, third-party and customer audits - QSP-56-01 • Analyzing and evaluating quality system performance and customer satisfaction data and trends - QSP-56-01, QSP-81-01, QSP-82-01, and QSP-85-03
Audit Areas	Management, Customer Service, QA
Audit ISO 9001	5.6 Management review 8.2.2 Internal Audit 8.2.3 Monitoring and measurement of processes

9 MONITORING CUSTOMER SATISFACTION	
Purpose	To process customer feedback and complaints and to measure customer satisfaction.
Process Owners	Customer Service, QA
Sub-Processes and Procedures	• Receiving and logging customer feedback and complaints - QSP-82-01, QSP-85-03 • Processing and responding to customer complaints - QSP-85-03 • Gathering of information and data about customer satisfaction - QSP-82-01 • Analyzing, reporting and presenting customer satisfaction information and data (preparing reports, plotting charts, holding meetings, etc) - QSP-56-01, QSP-81-01, QSP-82-01, QSP-85-04
Audit Areas	Customer Service, Management, Sales, QA
Audit ISO 9001	8.2.1 Customer satisfaction

10 MANAGEMENT POLICIES, PLANNING AND COMMITMENTS	
Purpose	To define the quality policy and quality objectives, to plan the quality management system (QMS), and to implement management commitments.
Process Owners	Management, QA
Sub-Processes and Procedures	• Establishing quality policy - MAN 5.3 • Establishing and monitoring of quality objectives - QSP-54-01, QSP-56-01, QSP-81-01, QSP-82-01, QSP-82-02, QSP-85-03

	• Planning the quality management system - MAN 5.4, QSP-56-01, QSP-85-01 • Defining responsibilities and authorities - MAN 5.5, MAN-ADD-01 • Appointing Management Representative - MAN 5.5
Audit Areas	Management, QA
Audit ISO 9001	4.1 General requirements 5.1 Management commitment 5.2 Customer focus 5.3 Quality Policy 5.4 Quality system planning 5.5 Organization and communication 8.4 Analysis of data

11 MANAGEMENT REVIEW	
Purpose	To review the suitability and effectiveness of the quality system; to consider changes to the quality system, quality policy and quality objectives, and to identify opportunities for improvement.
Process Owners	Management, QA
Sub-Processes and Procedures	• Presentation, discussion and evaluation of review input information - QSP-56-01, QSP-81-01 • Determining changes required (if any) for the quality policy, quality objectives and the quality management system - QSP-54-01, QSP-56-01 • Identifying opportunities for improvement and establishing quality objectives - QSP-54-01, QSP-56-01, QSP-85-01
Audit Areas	Management, Admin, Marketing/Sales, R&D, Production, QA
Audit ISO 9001	5.6 Management review 6.1 Provision of resources

12 HUMAN RESOURCES	
Purpose	To define competency requirements, provide training, and ensure awareness about quality-related issues.
Process Owners	Admin, Management
Sub-Processes and Procedures	• Determining competency requirements for jobs/positions affecting product quality - QSP-62-01 • Providing training and/or taking other actions to satisfy competency requirements - QSP-42-03, QSP-62-01 • Evaluating the effectiveness of training - QSP-62-01 • Providing awareness programs to ensure employee motivation, empowerment, and knowledge of quality-related issues. - QSP-62-01
Audit Areas	For process management: Admin; For implementation: All areas
Audit ISO 9001	6.2 Human resources

13 PLANT, FACILITY AND EQUIPMENT	
Purpose	To ensure appropriate and adequate facilities, production equipment and supporting services.
Process Owners	Technical Services, Management
Sub-Processes and Procedures	• Plant, facility and equipment planning - MAN 6.3, QSP-71-01 • Maintaining plant, facilities and manufacturing process equipment - QSP-63-01, QSP-64-01, QSP-76-01
Audit Areas	All areas

Audit ISO 9001	6.3 Infrastructure 6.4 Work Environment

14 INFORMATION RESOURCES (DOCUMENT CONTROL)	
Purpose	To control documents related to products, manufacturing processes and the quality system; and to control quality records.
Process Owners	All managers/supervisors (coordinated by QA)
Sub-Processes and Procedures	• Establishing documents needed by the organization - QSP-42-01, QSP-73-01 • Reviewing and approving documents - QSP-42-01 • Controlling document revisions and distribution (availability) - QSP-42-01, QSP-73-02 • Managing retention, storage, and disposition of records - QSP-42-03
Audit Areas	For process management: QA; For implementation: All areas
Audit ISO 9001	4.2 Documentation requirements

15 MEASURING AND MONITORING EQUIPMENT	
Purpose	To identify, maintain and calibrate monitoring and measuring equipment.
Process Owners	QA, Technical Services
Sub-Processes and Procedures	• Selecting monitoring and measuring equipment - QSP-71-01, QSP-73-01, QSP-76-01 • Calibrating monitoring and measuring equipment - QSP-76-01 • Controlling monitoring and measuring equipment - QSP-63-01, QSP-64-01, QSP-76-01
Audit Areas	Production, Technical Services, QA, R&D
Audit ISO 9001	7.6 Control of monitoring and measuring equipment

16 CONTINUAL IMPROVEMENT	
Purpose	To continually improve the quality management system, processes and products.
Process Owners	All managers/supervisors (coordinated by QA)
Sub-Processes and Procedures	• Collecting and analyzing quality performance data - MAN 8.4, QSP-74-01, QSP-81-01, QSP-82-01, QSP-82-02, QSP-83-01 • Handling and evaluating customer complaints - QSP-85-03 • Requesting and implementing corrective and preventive actions - QSP-85-04 • Establishing, reviewing and updating the quality policy - QSP-56-01 • Establishing, implementing and monitoring quality objectives - QSP-54-01, QSP-56-01 • Improving the Quality Management System - QSP-56-01, QSP-85-01
Audit Areas	All areas
Audit ISO 9001	8.5 Improvement

REVISION HISTORY - SECTION 9

Date	**Change Description**	**Revision**
01/14/16	Added NIST Handbook 150 references. See ECR #70238 for details.	J