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QUALITY ASSURANCE PROGRAM PLAN (QAPP)

PROGRAM: Insert the name of the program here.

CONTRACT NUMBER: *Insert the contract number here.*

REQUISITION NUMBER: Insert the requisition number here.

CUSTOMER: *Insert the name of the customer here.*

PROGRAM TEAM MEMBERS

Name Insert the name of team members here. Function Insert members function here.

Prepared by: *Name of the author of this QAPP and title.* Date: *Date prepared.*

Approved by: <u>Approvers name and title.</u> Date: <u>Approval date.</u>

Add additional approvers as needed. Approvers will typically include the Quality Management and the Program Manager. Include spaces for customer approval if required by contract.

Reviewed by: <u>*Reviewers name and title.*</u> Date: <u>*Review date.*</u>

Add additional reviewers as needed. This will typically include the local customer representative and possibly customer contacts.

Distribution:

Add a list of persons to whom a copy of this QAPP has been distributed. This will typically include the program team, internal customer representatives, and the customer if required by contract. Consider distribution to key support personnel from Operations and business unit (SQA, Sourcing, Subcontracts) and Engineering as well as any applicable business unit members and management.

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Revision Record

Date	Amended by:	Nature of Change	

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Note: Items in Aqua are requirements of AS9100, "Quality Management Systems – Requirements for Aviation, Space and Defense Organizations," that are in addition to ISO 9001. Delete them if they don't apply to this Program.

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1.0 Introduction

General Dynamics-OTS, Inc. is dedicated to ensuring customer satisfaction by providing quality products and services to our customers and continuously improving all business activities. GD-OTS maintains a Quality Management System that is ISO9001 certified *(facilities with other certifications such as AS9100 may add reference to them here)*. This Quality Management System is used for the management of all quality related activities for all contracts.

1.1 Purpose and Scope

This Quality Assurance Program Plan (QAPP) describes the policies and procedures for achieving the quality requirements for the *insert the name of the program* Program. This plan incorporates, by reference, the Quality Management System described in the Quality System Manual. Unless otherwise noted in this QAPP, the policies, procedures, and work instructions referenced in the GD-OTS Quality System are applicable. This QAPP describes those requirements in general and documents the requirements specific to this contract that are not covered by the general Quality Management System.

This QAPP defines the system followed to ensure product quality and compliance to contractual requirements in all aspects of the *add the name of the program* Program. This plan provides the basis for meeting the Statement of Work (SOW) and the Quality requirements of contract *add the contract number here.* This plan provides the overall framework for program quality activities.

Add here any other specific introductory details pertinent to the specific program being described and a brief description of the program.

1.2 Approvals and Revision

Describe here the persons who review and approve this document (e.g. Customer, local Government Quality Assurance Representative, Program Manager, SBU Director, etc.). Describe the requirements for handling and approving revisions to this document.

2.0 References: (Note: Latest revision applies unless otherwise noted)

Document

Description

ANSI/ISO/ASQ Q9001 AS9100 Quality Management Systems - Requirements Quality Management System - Requirements for Aviation, Space and Defense Organizations Quality System Manual

Quality System Manual Add to this table additional documents referenced by contract.

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3.0 Definitions

Program: Coordinated and managed activities for the purpose of supplying, within the established schedule, a unique product to the specified requirements.

Product: Result of activities or processes and may include service, hardware, processed materials, software, or a combination thereof.

Quality Plan: The document identifying specific quality practices, resources, and sequences of activities relevant to the Program Contract.

Quality System: The organizational structure responsibilities, procedures, processes, and resources for implementing quality management.

Subtier Supplier: A supplier that provides products or services through direct contact with a GD-OTS supplier or subcontractor.

Supplier: A direct subcontractor, contractually providing products or services to GD-OTS.

4.0 Quality Management System

4.1 General Requirements

GD-OTS maintains a Quality Management System that is compliant with the requirements of ISO9001 and AS9100. This system is certified and registered through a third party assessor. The system consists of the top level Quality Systems Manual, Procedures, Work Instructions, and Records. This system is designed to assure product quality, customer satisfaction, adherence to contractual requirements, and continuous improvement of products and business processes.

Contract Specific Requirements: Add here any specific quality system requirements required by the contract.

4.2 Documentation Requirements

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The general Quality Management System is documented in the top level GD-OTS Quality Systems Manual. A system of procedures and work instructions has been developed and maintained to effectively implement the Quality Management System. This QAPP integrates the general Quality Management System with the requirements of contract *insert contract number and title here*. The requirements imposed by the general Quality Management System apply to this contract except as noted in this QAPP. This QAPP provides guidance to personnel associated with the *insert program name* Program with regard to exceptions or additional quality system requirements imposed by this contract.

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Additional procedures and work instructions specific to the quality management of this program will be written as required to assure compliance with all contractual requirements. All quality system documents and revisions are reviewed and approved by appropriate authority and are controlled through posting on the GD-OTS Intranet.

Records of quality activities are maintained as required by the general Quality Management System. The required records are identified and retention locations and time periods established. Any additional records required by the *insert program name* contract or any retention requirements differing from standard requirements are noted in this QAPP.

Contract specific documentation requirements: Add here any specific documentation requirements required by contract. For example, if a QAPP is a contract requirement, note that requirement here.

Contract specific record requirements: Add here any record/record retention requirements that are required by contract. This could include records required of suppliers and sub-tier suppliers. For AS 9100, state that records be available for review by customers and regulatory authorities in accordance with contract or regulatory requirements.

Contract specific documents: List here the numbers and titles of any documents written specifically for the quality management of this program. Include program specific Instructions, Test Procedures, Process Instructions, etc.

5.0 Management Responsibility

5.1 Management Commitment

The management of GD-OTS is committed to maintaining a Quality Management System that ensures customer satisfaction, compliance to specified requirements, and continuous improvement. This commitment is communicated through the deployment of our Quality Policy throughout the organization and the flow down of quality, customer, and improvement related goals. The suitability and effectiveness of the Quality Management System is evaluated at regularly scheduled Management Reviews.

5.2 Customer Focus

The management of GD-OTS has established the SBU structure to assure that the business is focused on identifying customer needs and requirements and assuring that customer satisfaction is enhanced. Each program is assigned a Program Manager and a cross functional Program Team to focus on the requirements of each contract. The *insert the name of this program* Program resides within the *insert the name of the SBU this program is in SBU*.

5.3 Quality Policy

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It is our Policy to deliver products and services that perform as designed, every time! Our Quality Focus is to:

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- Meet our customer's needs and expectations
- Create a culture that instills quality and continuous improvement in everything we do
- Eliminate defects through prevention

5.4 Planning

The activities of the Quality Management System are planned and documented in procedures and work instructions. Planning for the *insert the name of this program* Program is carried out through this Quality Assurance Program Plan. The QAPP integrates the general Quality System with the unique requirements of the *insert the name of this program* Contract. To assure full understanding, the QAPP in draft form is reviewed by members of the Program Team prior to final approval and release. The QAPP is made available to all members of the Program Team by posting on the GD-OTS Intranet *or as defined in site instruction*. Planning of verification requirements and activities specific to this program and its contractual requirements are carried out by the Test Program Board that is established by the Program Manager and chaired by the Program Quality Engineer.

5.5 Responsibility, Authority, and Communication

The *insert the name of this program* Program is part of the *insert the name of the SBU this program is in* SBU. The *insert the name of this program* Program Manager is the authority having primary responsibility for coordination of all activities in support of the *insert the name of this program* contract.

The Vice President of Operations has the responsibility for maintaining a Quality Management System compliant with the requirements of ANSI/ISO/ASQ Q9001 (add SAE AS9100 if a contractual requirement). The Vice President Operations has the organizational freedom to resolve matters pertaining to quality. The *insert the name of this program* Quality Engineer has been delegated the authority for all matters pertaining to Quality Assurance for the *insert the name of this program* contract. The Quality Engineer is responsible for quality planning, contractual compliance regarding matters of quality, documentation of quality requirements and procedures, ensuring program team members are aware of the program quality requirements and is the contact person for all matters concerning quality.

If the program involves software, describe here assignments and provisions made for Software Quality Assurance.

You may add here a diagram showing positions and reporting relationships within the program team.

5.6 Management Review

The senior management of GD-OTS conducts an annual review of the Quality Management System for ongoing suitability and effectiveness of the system and attainment of established quality goals. In addition,

- The leadership of each SBU conducts a periodic review of the Quality Management Operating System for on going suitability and effectiveness of the system and attainment of quality objectives.
- Program Executive Management conducts formal reviews of customer satisfaction. Improvement goals and activities are determined as a result of these reviews.

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6.0 Resource Management

6.1 Provision of Resources

An interdisciplinary team has been assigned to support the *insert the name of this program* Program. This includes Programs, Finance, Sourcing, Engineering, Contracts, Manufacturing Engineering and Quality Assurance.

6.2 Human Resources

Team member competencies are based on education, training, skills, and experience. Where required, training is provided to ensure that work affecting quality is performed in such a way as to meet the requirements and objectives of GD-OTS and *insert name of the customer*. (If there are any special skills required by the contract discuss how training on these skills will be accomplished here.)

6.3 Infrastructure

GD-OTS has provided the infrastructure necessary to meet the requirements of the *insert the name of this program* contract and applicable regulatory requirements. This includes provision of buildings, work space, utilities, process equipment, tooling and supporting services.

6.4 Work Environment

GD-OTS maintains an active EHS program to assure the safety of employees and that company and customer requirements are met.

7.0 Product Realization

7.1 Planning of Product Realization

The Program Team coordinates the planning and development of the processes needed for product realization and ensures that these processes are consistent with the requirements of other processes within the quality management system.

The following are determined in the planning of product realization:

- program quality objectives
- product requirements
- process requirements

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- documentation and records requirements
- resources requirements
- required verification, validation, monitoring, inspection and test activities
- criteria for product acceptance
- configuration management appropriate to the product
- identification of resources to support operation and maintenance of the product

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The output of this planning is in the form of this Quality Program Plan and lower tier work instructions and plannings.

7.1.1 Project Management

For AS9100 Requires planning and management of product realization in a structured and controlled manner to meet requirements at acceptable risk, within resource and schedule constraints (describe Program or Management Plan for the project.

7.1.2 Risk Management

For AS9100 Requires risk management process including

- assignment of responsibilities for risk management
- definition of risk criteria (likelihood, consequences, risk acceptance)
- identification, assessment and communication of risk throughout product acceptance
- identification, implementation and management of actions to mitigate risks that exceed the defined risk acceptance criteria
- acceptance of risks remaining after implementation of mitigating actions

7.1.3 Configuration Management

For AS9100 Requires establishing and documenting and maintaining a configuration management process appropriate to the product that includes

- configuration management planning
- configuration identification
- change control
- configuration status accounting
- configuration audit

GD-OTS will maintain Configuration Management for *insert program name* in accordance with documented procedures.

7.1.4 Control of Work Transfers

For AS9100 Requires process to plan and control the temporary or permanent transfer of work (ex. one GD facility to another, from GD-OTS to a supplier, from one supplier to another supplier) and to verify the conformity of the work to requirements. Work transferred on a temporary basis is controlled and validated to assure continued quality.

7.2 Customer Related Processes

The *insert the name of this program* contract has been reviewed by the *insert the name of this program* Team contract representative to assure that all requirements have been adequately defined, documented,

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understood and agreed upon. The review includes evaluation of special requirements and risks (e.g., new technology, short delivery time scale) have been evaluated. Input from other disciplines within the Program Team has been actively sought and documented as part of the review process. Any amendments to this contract are subject to review via a Contract Review and Flowdown, prior to acceptance and incorporation.

The *insert the name of this program* Program Manager is responsible for coordinating and assuring effective communication in all matters with *insert the name of the customer*.

7.3 Design and Development (*Note: Add this section only if design is part of the contract. If the contract is a build to print contract, indicate not applicable.*)

The design process consists of System Design, Configuration Item Design, Configuration Item Integration and Test, and Systems Integration and Test. The design process is governed by *PD-PRO-1 Definition*. A *Management Plan* is developed as a top level plan to guide the program technically. *Management Plan* guides the design process and plans for the development and scheduling of activities such as Design Reviews, development of Technical Performance Measurements, Test Readiness Reviews, etc. The Integrated Test Program Plan (ITPP) is developed to guide the design validation process and the Design Verification Test Plan is developed as a method to verify that the requirements of the System Requirements Specification have been satisfied. The *Project Lead* is assigned the responsibility for development and implementation of the *Management Plan*. (*Note: If site does not employ use of an ITPP, please indicate method for specifying validation testing.*)

Design output is in the form of product drawings that are placed under configuration. Revisions are controlled through the Change Notice (CN) process.

Discuss here the use of Log Books if they are to be allowed for this program.

The following apply to the *insert the name of this program* Program: Management Plan# = *Insert applicable Mgt Plan number if applicable* ITPP # *Insert applicable ITPP number* DVTP # *Insert Applicable Design Verification Test Plan number*

Discuss here any specific contractual requirements of processes pertaining to the design process for this programs. This may include the following items: Requirements for FMECA analysis Qualification testing requirements Key characteristics

Additional discussion of design and development requirements may be appropriate if AS9100 is a contract requirement, consult AS9100 standard. Verify that Engineering is addressing additional requirements in their documentation.

7.4 Purchasing

All purchased material for the *insert the name of this program* Program are governed by the GD-OTS Quality System Manual paragraph 7.4 and associated Quality System Procedures (QSP).

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Products are purchased from approved suppliers. An approved Supplier List (ASL) is maintained. Procedures exist for survey, review, and approval of suppliers for addition to the ASL. Approved suppliers are subject to periodic resurvey to maintain approval. Supplier quality performance is measured and the performance of suppliers not meeting quality expectations is reviewed to determine necessary improvement actions required of suppliers. **Suppliers failing to maintain GD-OTS quality requirements are removed from the ASL**. A similar process is followed for the approval of suppliers of Special Processes and a Special Process ASL is maintained. Supplier Quality Assurance (SQA) assures that general quality requirements and special quality requirements identified in this QAPP are flowed to suppliers and sub-tier suppliers as required through the addition of appropriate text that is added to Purchase Orders for products (reference QSP-PRO-52, Quality Clauses). All purchased products are subject to verification through the use of receiving inspection, source inspection, certification, or other appropriate means. SQA determines which requirements are to be verified at the supplier's facility by the Supplier (Supplier Excellence Program/*DTS program as applicable*), at the supplier's facility by a GD-OTS representative (Source Acceptance) and/or at Incoming Appraisal. Records of verifications are maintained.

GD-OTS maintains a Supplier Excellence Program through which suppliers may be Qualified for Dock to Stock shipment based on Quality System audit results, supplier history, supplier rating, delivery performance and other factors. Potential SEP suppliers are subject to a rigorous approval process. Once approved as an SEP supplier, individual products are qualified on a part by part basis. *If site does not utilize SEP Program, please note dock to stock details here or omit paragraph if no dock to stock program.*

If nonconforming material is received from a supplier it is subject to identification, quarantine, and material review by authorized personnel. Formal root cause analysis and written corrective action plans are required from suppliers when nonconforming material is supplied.

Discuss here any special purchasing requirements stipulated by contract such as requirements for customer source inspection, customer access to supplier's facilities, arrangements for and method of release if customer source inspection is required and any Quality System requirements that must be flowed down to suppliers. If Key Characteristics or First Article Inspection requirements are specified, discuss flow down process to suppliers.

If there are any special or significant purchased items they may be documented here as well as any critical criteria to be met. Note any special receiving inspection requirements.

When required address

- Customer approved suppliers and special process sources.
- Requirements for supplier to notify GD-OTS of changes in product/process definition and obtain GD-OTS approval.

7.4.3 Verification of Purchased Product

7.5 Production and Service Provision

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7.5.1 Control of Production and Service Provision Planning for production considers,

- the establishment of process controls and development of control plans where Key characteristics have been identified.
- Identification of in-process verification points when adequate verification of conformance cannot be performed at a later stage of realization
- The design, manufacture, and use of tooling so that variable measurements can be taken, particularly for Key characteristics

Manufacturing, inspection, test, and associated support activities are carried out under controlled conditions. Where required for the *insert the name of this program* Program, specific procedures, drawings, specifications, and work instructions will be created and made available where needed to assure proper control of activities to meet contractual requirements.

Control conditions include,

- Accountability for all product during manufacture
- Evidence tat all manufacturing and inspection operations have been completed as planned
- Provision for the prevention, detection, and removal of foreign objects
- Monitoring and control of utilities and supplies such as water, compressed air electricity and chemical products to the extent they affect product quality
- Criteria for workmanship is stated in clear understandable manner.

7.5.1.1, .2, .3, .4, &.5 Production Documentation, Process Changes, Equipment and Tools, and Control of Service Operations

Production operations are carried out in accordance with approved data such as drawings, parts lists, manufacturing routers, inspection documents etc. Changes to production processes are performed by authorized personnel. Processes are in place to assure changes requiring customer/regulatory authority approval are processed in accordance with requirements. Production equipment is validated prior to use and maintained and inspected according to documented procedures. Validation prior to production includes verification of first article. Preservation/condition checks are performed on equipment and tooling in storage. y.

First Article Inspection is performed in accordance with GD-OTS procedures. Discuss contract specific First Article Inspection requirements here. If AS 9102 is a contract requirement provide sufficient detail to assure compliance with all the requirements of the Standard.

Discuss other specific requirements of these paragraphs as appropriate.

7.5.2 Validation of Processes for Production and Service Provision

Use of special processes that cannot be fully verified by subsequent monitoring and measurement are identified, qualified and approved **prior to use**.

7.5.3 Identification and Traceability

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The implementation of detailed work instructions and production paperwork controlling shop in-process materials provide an established routine for ready identification of **product configuration**, inspection and test status. The principal method of maintaining evidence of material acceptance, both in process and final, is through the use of specific stamps by Quality Control. Site Quality procedures identify use of each stamp, associated user responsibility and its application. The shop paperwork system works in consonance with the QC stamp application in controlling and identifying status of parts and/or lots. Records show acceptance through processes and operations via the acceptance stamp. *If product is processed in facilities with other means of identifying material status, delete this paragraph and discuss those methods here.*

Discuss here any specific identification and traceability requirements required by this contract. Discuss how serial numbers or lot numbers will be used on this product.

If the customer will be supplying any materials or tooling for this contract make specific reference to them here. Discuss provisions for how the materials will be handled and cared for and any special reporting requirements that may be required by the contract and how they will be addressed.

Discuss any specific requirements for packaging, preservation or handling of this product that are unique to the product or required by contract.

7.6 Control of Measuring and Monitoring Equipment

All required measurements are identified and measuring and monitoring devices are selected in order to assure product quality requirements are met. All measuring and monitoring equipment are evaluated so that their measurement uncertainty is known and are used in processes consistent with their uncertainty. All instruments for measuring and monitoring conformance characteristics are calibrated and identified so that calibration status can be determined. Appropriate methods are employed to safeguard measuring and monitoring equipment from inadvertent adjustment that would invalidate the measurement results. They are controlled to prevent damage or change due to handling, storage, and use and stored to prevent deterioration.

Software used in the measuring and monitoring process is validated prior to use. Special testing software developed for use meets the requirements of the design or planning output. A documented change process is implemented whereby modified software is rechecked and revalidated.

All instruments and monitoring equipment are assigned a unique identification and calibration is performed on a scheduled basis against standards traceable to NIST, a known and accepted physical constant, or other recognized and accepted standard under documented controlled conditions including environmental conditions. In cases where no national or international standard exists, the basis for calibration is documented. Methods for calibration are documented and maintained, and the calibration system utilizes a recall process for equipment due for calibration. Results of calibrations are recorded and documented as per procedures. Any devices found out of calibration are documented and reported. Any impact to product, both in plant and delivered, is evaluated and appropriate action taken to correct deficiencies.

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Should any measuring and monitoring equipment be the property of the customer note it here and discuss provisions for calibration (provided by customer, GD-OTS?) and traceability. Note here the need for any special Quality Information Equipment.

8.0 Measurement, Analysis and Improvement

8.1 General

GD-OTS plans and implements processes for monitoring, measurement, analysis and improvements in order to ensure and demonstrate conformity of product and effectiveness of the quality management system. Information obtained through monitoring, measurements and analysis is used to drive continuous improvement.

When contractually required discuss statistical techniques and where they are applied, design, Process Control, Inspection, Failure mode and effects analysis etc.

8.2 Monitoring and Measurement

The Program Manager of the *insert the name of the SBU this program is in* SBU is responsible for assessing customer satisfaction. Executive reviews of customer satisfaction are scheduled in accordance with procedures. The *insert the name of this program* Program Manager is the primary contact for *insert the name of the customer* regarding all matters concerning customer satisfaction issues.

Internal quality system audits are planned and scheduled to continually assess compliance to policies, procedures and other requirements and to identify opportunities for improvement. Audits are performed on each area of the quality management system by a trained team or person who is independent of the area being audited. These audits insure the management system is meeting ISO9001*and AS9100* and other stated requirements. Audit findings are documented and timely corrective actions are taken by the responsible management. Findings are evaluated to determine if nonconforming product has been generated, if yes, it is controlled in accordance with nonconforming material requirements. Follow-up verification determines the effectiveness of the corrective actions. Procedures have been written to define the audit system. Schedules for audits are made based on past deficiencies and element importance to the system. Results of audits are recorded and reported to management.

If the customer has any requirements for special audits that are beyond the scope of our routine ISO internal audits note them here.

Quality Management System processes are monitored and measured to assess the ability of the processes to achieve planned results. When planned results are not achieved, corrective actions are taken to ensure conformity of products and improve the effectiveness of the process.

Suitable methods of measuring and monitoring required characteristics of the *insert the name of the produced for this program* are planned and used to assure that all requirements are met. Results of measurements are documented and recorded. Identification of the responsible authority for release of finished products or services are defined and recorded. Product is not released until all the specified activities have been satisfactorily completed.

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Discuss here when Key characteristics are a requirement.

When Sampling plans are used as a means of product acceptance they are statistically valid and appropriate for use. The plan precludes acceptance of lots whose samples have known nonconformities. When required the plan is customer approved.

Discuss here any special requirements for release of product such as customer source inspection requirements. Discuss timing and communication requirements.

Note here any contractual requirements for identification and monitoring of key characteristics, fault proofing, special testing or inspection requirements, use of statistical process control, etc. and how they will be handled.

8.3 Control of Nonconforming Product

At GD-OTS, Identification, segregation, control and disposition of nonconforming product are performed in accordance with GD-OTS procedures. Nonconforming product or material is tagged or otherwise conspicuously marked and segregated from conforming items to prevent reintroduction into processing and/or unauthorized work. Any prior evidence of acceptance is nullified and no further processing of this material occurs until a documented disposition or special quality instruction is issued.

Both internal and supplier nonconformances are fully documented. All documentation provides for cause determination, corrective action and approved Material Review Board (MRB) disposition, as required. Test failures receive Engineering and QE analysis and may require an expanded Failure Analysis Board (FAB) for cause and corrective action determination and corrective action effectiveness.

Nonconformances are dispositioned by a Material Review Board (MRB) established for the *insert the name of the program* Program. *Discuss the make-up of the MRB for this program and the level of MRB authority given by the contract. Discuss any special methods by which waivers are to be submitted for approval. Include identification of any special forms that are required to be used.*

Discuss here any Material Review authority that has been delegated to suppliers.

Disposition recommendations beyond to the authority of local Material Review Board will be submitted to customer in accordance with contract requirements.

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GD-OTS Quality system provides for timely reporting of delivered nonconforming product to *insert the name of the customer* when product reliability or safety may be affected.

8.4 Analysis of Data

Data obtained through measurement and monitoring of products and processes are analyzed to drive corrective actions, preventive actions and continuous improvement. Analysis also provides information regarding the suitability and effectiveness of the quality management system.

8.5 Improvement

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GD-OTS is committed to continually improving it business processes and products. This is accomplished through deployment of the quality policy, quality objectives, and quality system processes and procedures. Information used for continuous improvement comes from internal audits, customer audits, supplier audits, corrective and preventive actions, analysis of data and the quality management review process.

Discuss here contractual requirements for continuous improvement or reduction of variation and how they will be addressed.

Corrective and Preventive Action are handled in accordance with procedures for both internal and supplier issues. The corrective/preventive action system provides for comprehensive identification and evaluation of deficiencies causing actual or potential nonconformances. The system also provides for the completion of actions to resolve problem areas as well as the initiation of preventive action changes to procedures and documents resulting from corrective/preventative actions.

If a Corrective Action Board (CAB) is a contractual requirement, discuss here how the CAB will function for this contract.

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