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SUMMARY OF CHANGES

ISSUE DATE	REV. NO.	CHG NO.	REVIEW
Unknown	Rev 0	Original	0
31 Aug 04	Rev 1	0	0
26 Feb 10	Rev 2	0	0
18 Sep 15	Rev 3	0	0
13 Dec 17	Rev 3	0	1
26 Jan 18	Rev 4	0	0

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INTRANET QUALITY SYSTEM CONTROLLED**COMMANDER'S APPROVAL PAGE****LETTERKENNY ARMY DEPOT****QUALITY SYSTEM**

The Quality System Manual (QSM) applies to all activities reporting to the Commander of Letterkenny Army Depot (LEAD) who directly or indirectly have an impact on the quality of our products and services.

QUALITY POLICY

LEAD is committed to customer satisfaction by providing products and services that fulfill requirements and exceed expectations through continuous measurement, evaluation and improvement.

QUALITY OBJECTIVES

LEAD's Quality Objectives are expressly stated in LEAD Strategic Business Plan under Commanders' Strategic Initiative, and established throughout depot organizations.

QUALITY MANAGER

The Director of Product Assurance has been delegated as the Quality Manager (QM) and has the direct responsibility and authority for ensuring implementation of LEAD's Quality System, Policy, and Objectives.



STEPHEN W. LEDBETTER

Colonel, LG
Commanding

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INTRANET QUALITY SYSTEM CONTROLLED**QUALITY MANAGER'S APPROVAL PAGE****LETTERKENNY ARMY DEPOT****QUALITY SYSTEM MANUAL**

The purpose of this manual is to outline LEAD's Quality Management System (QMS). LEAD's QSM is a document stating the Quality Policy and describing the QMS of the depot as a supplier of quality products and services. The QSM outlines the importance of compliance with customer and regulatory requirements. Compliance is further discussed in depot QSPs (See Appendix B) maintained on the depot LEAD SharePoint. LEAD maintains comprehensive quality management processes to address business operations throughout the entire product cycle from initial proposal through customer acceptance and subsequent support services. LEAD's QMS is complete and responsive to the requirements of International Organization for Standardization (ISO) 9001:2008.

Information in this QSM is depot unique and is published to ensure that LEAD's Quality Policy is understood and implemented. It is the responsibility of all personnel to ensure compliance with this policy and all supporting QSPs and Work Instructions (WIs), and to report any known discrepancies.

Should contradiction exist between this manual and other regulatory guidance, the regulatory guidance shall take precedence over this manual. The QSM will be updated to comply with regulatory guidance.

The proponent agency of this publication is LEAD, Directorate of Product Assurance (DPA). Send comments and suggested improvements to the Director of Product Assurance, Letterkenny Army Depot, ATTN: AMLD-QA, Chambersburg, PA 17201-4150.

This manual replaces the Quality System Manual, 13 Dec 17. All previous editions shall be discarded.



TODD E. BLACK
Quality Manager

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INTRANET QUALITY SYSTEM CONTROLLED**DEPOT PROFILE**

LEAD was established in December 1941 as the Letterkenny Ordnance Depot with the initial mission being to store ammunition and supplies. Letterkenny has grown over the past 70+ years to provide a variety of products and services to the Department of Defense (DOD). Currently, LEAD is a maintenance depot performing receipt, storage, issue, maintenance, and disposal of assigned commodities, as well as providing installation support to tenant activities and operating such other facilities as may be assigned.

LEAD is located in the south-central portion of the Commonwealth of Pennsylvania in Franklin County, approximately 5 miles north of Chambersburg. The installation is regionally situated between the metropolitan areas of Pittsburgh, Pennsylvania, 180 miles to the west; Philadelphia, Pennsylvania, 155 miles to the east; Washington, D.C., 90 miles to the south; and Baltimore, Maryland, 92 miles to the southeast. This ideal location has enabled the depot to provide quality products and services to a major portion of the world's armed forces, both domestic and foreign in a timely manner.

Entering into its eighth decade of providing support to the Soldier in the field, LEAD has made modernization of facilities and equipment key to its future. These facilities, coupled with LEAD's 18,281 acres of land and its work force, ensure the depot's ability to meet the demands of expanded missions.

The depot's primary mission is maintenance, as well as providing air defense and tactical missile support to DOD. A complete discussion of these missions is contained in the depot Strategic Plan, available from the depot Business Development Office (BDO).

LEAD is a government installation predominately operated by civilian federal employees and commanded by a military officer of the United States Army who is assisted by a Deputy to the Commander.

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INTRANET QUALITY SYSTEM CONTROLLED**1.0 SCOPE.****1.1 General**

The QSM specifies requirements for a quality management system that consistently provides products and services that meet customer and applicable statutory and regulatory requirements and enhances customer satisfaction through the effective application of QMS and processes for continuous improvement of the system and the assurance of conformity to customer and any legal *and authority* requirements.

1.2 Application

All requirements of the QSM are intended to apply to LEAD and facilities supporting LEAD in its effort toward product delivery. The applicable standards include ISO 9001:2015 QMS requirements and the *Aerospace Standard (AS) 9110A QMS requirements for Aviation Maintenance organizations developed by International Aerospace Quality Group (IAQG)*. LEAD is not responsible for design control and therefore excluded from ISO 9001:2015 *and AS9110A*, Clause 8.3 – Design and Development of products and services.

NOTE: *AS9110 requirements are indicated in italics. Those italicized requirements only apply to process areas complying with AS 9110, i.e., HIMARS, TRMD, and PATRIOT New Build Launcher.*

1.3 QMS

The Commander has ultimate responsibility for the QMS, which applies to all activities at LEAD. The QMS is applicable to all personnel, organizations, and external providers who directly or indirectly have an impact on the quality of our products/services being provided to our internal and external customers. The QMS is based on the clauses in ISO 9001:2015. A brief overview of each clause in *ISO 9001:2015 with additional requirements of IAQG developed AS9110A* starting with Clause 4 – Context of Organization as they relate to LEAD is presented in this section.

1.4 QMS Summary**1.4.1 Context of Organization – Clause 4**

This clause focuses on understanding the internal and external issues both positive and negative that are relevant to LEAD's purpose and strategic direction and ability to achieve intended results of the QMS. Understanding the external context can be facilitated by considering issues arising from legal, technological, competitive, market, cultural, social and economic environments, whether international, national, regional or

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local. Understanding the internal context can be facilitated by considering issues related to values, culture, knowledge and performance of the organization.

1.4.2 Leadership – Clause 5

This clause focuses on commitment of Executive leadership to the QMS and communicating that commitment to the rest of the organization. The quality focal point is customer satisfaction, and as such, all policies and activities including the Quality Policy shall be designed as part of an organized process working to achieve this goal.

Management is accountable for developing and implementing an effective QMS that is reviewed periodically. Management is also responsible for developing quality policy and objectives and communicate them with the rest of the depot as part of continuous improvement of the QMS and to ensure that adequate resources are allocated to achieve requirements.

1.4.3 Planning – Clause 6

This clause focuses on proper steps required in planning for the QMS and any changes made to it. In planning stages, LEAD shall consider internal and external issues along with the needs and expectations of the interested parties to determine the risk and opportunities involved and take appropriate actions to address these risks and opportunities. For more information about risk management, refer to QSP 24 – Risk Management.

1.4.4 Support – Clause 7

This clause focuses on resources needed to establish, implement, and maintain the QMS and continually improve its effectiveness, and to enhance customer satisfaction. The adequacy of the facilities, utilities, infrastructure, work environment, personnel training, competence, and awareness, monitoring and measurement resources, and organizational knowledge are all discussed and determined under this section.

LEAD shall:

- determine and provide the persons necessary for effective implementation of its QMS and for the operations and control of its processes;
- determine the necessary competence for personnel performing work affecting conformity to product requirements;
- where applicable, provide training or take other actions to achieve the necessary competence or ensure competence on the basis of appropriate education, training, or experience, and to evaluate the effectiveness of the actions taken;

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- ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives;
- ensure that its personnel doing work are aware of LEAD quality policy and quality objectives and their contribution to the effectiveness of the QMS, including the benefits of improved performance and any implications of not conforming to the QMS;
- maintain and retain appropriate documented information or appropriate records of education, training, skills and experience as evidence of competence.

LEAD shall also provide and maintain the infrastructure necessary for the operation of its processes and to achieve conformity of products and services along with:

- buildings, workspace and associated utilities;
- process equipment (both hardware and software);
- supporting services (such as transport, communication, security, or information and communication technology and systems).

LEAD shall:

- determine and provide the monitoring and measuring resources;
- determine the knowledge necessary for the operation of its processes and to achieve conformity of products and services. This knowledge shall be maintained and be made available to the extent necessary.

LEAD shall

- maintain documented information required by international standards, customers, authority, legal, and statutory and regulatory requirements;
- maintain documented information necessary for the effective operation of the QMS;
- control and protect documented information to ensure its availability and suitability for use, where and when needed;

LEAD shall:

- *maintain a system to continually assess the availability of tools, technical data, and qualified personnel to ensure the safe completion of all Maintenance Repair and Overhaul (MRO) activities;*
- *coordinate activities to direct and control product configuration.*

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1.4.5 Operation – Clause 8

This clause focuses on planning, developing, implementing, and controlling processes needed for product realization and to meet product and service provisions. This includes operation planning and control, determining and reviewing the requirements of products and services and the type of control needed. LEAD shall also apply control to externally provided processes, products, and services and products and services released to the customer. LEAD shall also develop and implement control of nonconforming outputs.

1.4.6 Performance Evaluation – Clause 9

This clause provides guidelines with respect to all measurements, such as measuring customer satisfaction, internal audit results, nonconformity data, and all other data related to process, product, and services. The collected data must then be used to identify problem areas through statistical analysis of data and root cause analysis and to facilitate corrective and preventive actions leading to product and service improvements. Customer satisfaction, which is measured through customer communication, is the cornerstone of ISO 9001:2015. LEAD takes pride in customer satisfaction and this pride is documented through continuous review of all customer-related processes. Establishing effective lines of communication with the customer is essential to this requirement.

Periodic review of the QMS at planned intervals to ensure its continuing suitability, adequacy, effectiveness, and alignment with the strategic direction of LEAD is also part of the requirements of this clause.

1.4.7 Improvements – Clause 10

This clause focuses on opportunities for improvement, taking corrective actions, and dealing with nonconforming products and services. This includes developing and implementing actions necessary to meet customer requirements and to enhance customer satisfaction as part of a continuous improvement of the QMS to ensure its suitability, adequacy, and effectiveness for all interested parties.

1.5 LEAD Process Map

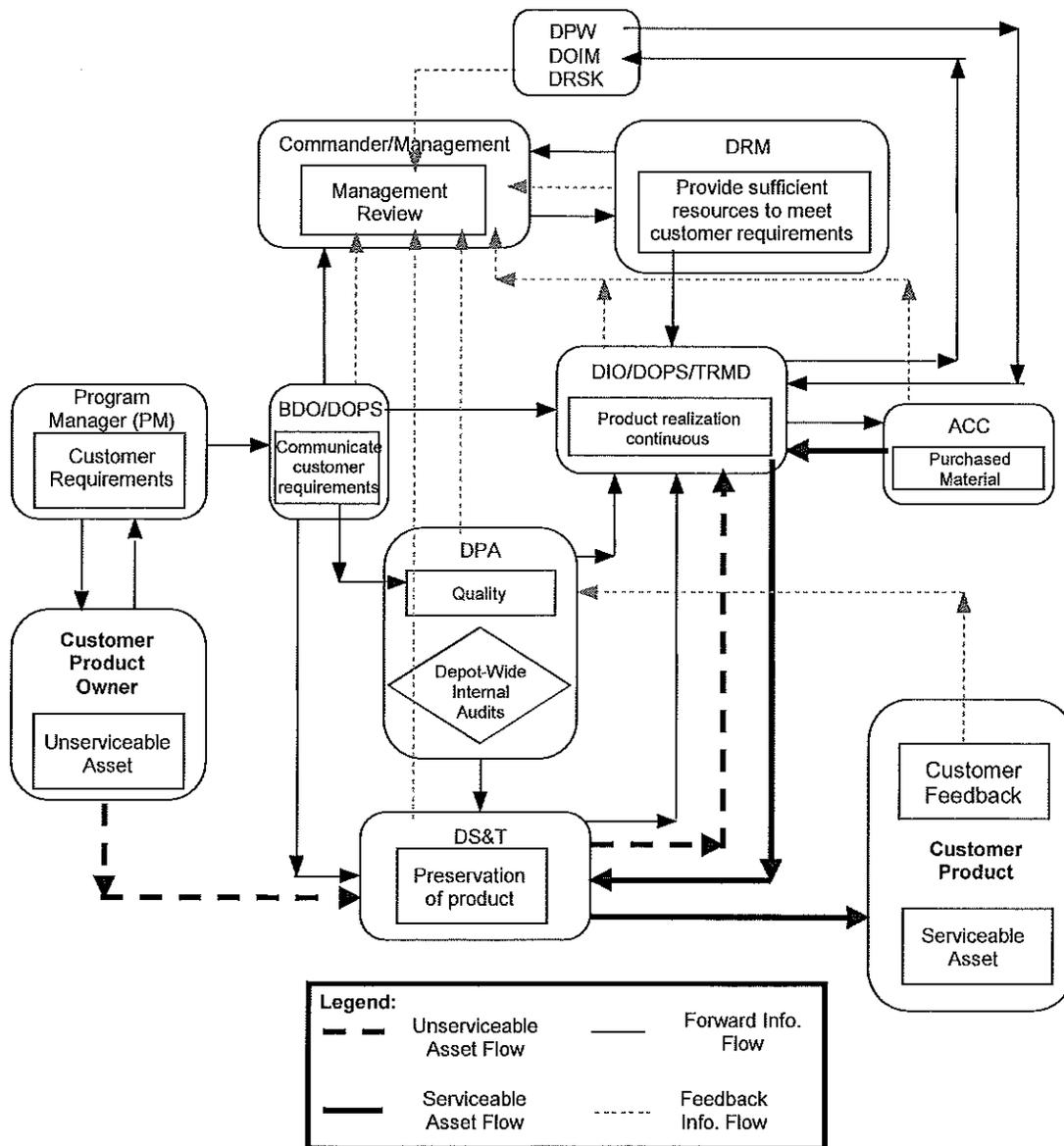
Various staff Directorate groups within LEAD interact with each other following a continuous improvement process as described in the process map below. These groups are Command Group, Business Development Office (BDO), Directorate of Industrial Operations (DIO), Directorate of Operations Planning and Support (DOPS), Theater Readiness Monitoring Directorate (TRMD), Directorate of Product Assurance

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(DPA), Directorate of Resource Management (DRM), Directorate of Supply and Transportation (DS&T), Army Contracting Command (ACC), Directorate of Public Works (DPW), Directorate of Risk Management (DRSK), and Directorate of Information Management (DOIM). The responsibilities of the various directorates are outlined in QSP 1, Management Responsibility.

LEAD PROCESS MAP



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See LEAD external website.

2.0 NORMATIVE REFERENCES.

Apply ISO 9001:2015, Quality Management Systems - Fundamentals and Vocabulary or the most recent edition of normative documents.

3.0 DEFINITIONS/ACRONYMS.

3.1 Use ISO 9001:2015, Quality Management Systems *and* AS9110A, *Quality Management Systems for Aviation Maintenance Organizations* vocabulary in TERMS and DEFINITIONS sections of these standards.

3.2 The term "product" also means "service" throughout LEAD and ISO 9001:2015 *and* AS9110A standards documents.

3.3 The terms "product" or "service" only apply to products and services intended for or required by, a customer or an interested party.

3.4 Statutory and regulatory requirements can also be expressed as legal requirements.

3.5 "business" can be interpreted broadly to mean those activities that are core to the purposes of the organization's existence, whether the organization is public, private, for profit or not for profit.

3.6 The list of acronyms contained in Appendix A of this document is applicable to this document and all LEAD QSPs.

4.0 CONTEXT OF ORGANIZATION**4.1 Understanding the organization and its context**

4.1.1 LEAD shall determine external and internal issues that are relevant to its purpose and its strategic direction and that affect its ability to achieve the intended result(s) of its QMS. LEAD shall monitor and review information about these external and internal issues.

LEAD Organizational Context are posted on the internet at our main website. It provides an explanation of who we are which is stated as "The premier DOD center of

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industrial and technical excellence for air defense tactical missile ground support equipment, mobile electric power generation equipment, Patriot missile recertification and Route Clearance vehicles.”

Our main page also provides what we do which is our mission statement stated as “Deliver superior maintenance, manufacturing, logistics, life cycle support and service worldwide to the joint Warfighter and our International Partners.” It also provides where we are going which is our vision statement “Letterkenny Army Depot is the Missile Readiness Partner for Industry, Government and the greatest Warfighters in the world.”

4.1.2 Issues can include positive and negative factors or conditions for consideration. Understanding the external context can be facilitated by considering issues arising from legal, technological, competitive, market, cultural, social and economic environments, whether international, national, regional or local. Understanding the internal context can be facilitated by considering issues related to values, culture, knowledge and performance of the organization.

Our external issues will change as we adapt and grow, therefore, these issues will be updated and reviewed periodically. Some of the current external issues include community and its growth, facilities issues, environmental issues, traffic issues, and competition for new workload.

Understanding the internal context can be facilitated by considering issues related to values, culture, knowledge and performance of LEAD. This also includes understanding the needs and expectations of interested parties as part of determining the scope of the Quality Management System. Our internal issues will change as we adapt and grow, therefore, these issues will be updated and reviewed periodically. Some of the current internal issues include technical & labor requirements, wages, mature and aging workforce, training requirements, funding, use of facilities internally, turnovers, knowledge base disappearing, and leadership culture/expectations.

4.2 Understanding the needs and expectations of interested parties

Due to their effect or potential effect on the LEAD's ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, LEAD shall determine:

- a) the interested parties that are relevant to the quality management system;
- b) the requirements of these interested parties that are relevant to the quality management system.

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The needs and expectation of our interested parties are discussed at management review meetings and the interested parties are tentatively identified as our customers and their customers, all external providers and vendors in our supply chain, all government and military employees and their families, all contractors, the surrounding community, and all relevant regulatory agencies.

4.2.1 LEAD shall monitor and review information about these interested parties and their relevant requirements.

4.3 Determining the scope of the quality management system

LEAD shall determine the boundaries and applicability of the QMS to establish its scope. When determining this scope, LEAD shall consider:

- a) the external and internal issues;
- b) the requirements of relevant interested parties;
- c) the products and services offered to customers.

4.3.1 LEAD shall apply all the requirements of ISO 9001:2015 standards except section 8.3 – Design and development of product and services.

4.4 Quality management system and its processes**4.4.1 General requirements**

4.4.1 LEAD has implemented a QMS that is continuously maintained while ensuring all customer and applicable statutory and regulatory requirements are met.

4.4.1.1 LEAD has established, documented, implemented, and maintained a QMS and will continually improve its effectiveness in accordance with (IAW) ISO 9001:2015 and *AS9110A international standards*.

4.4.1.2 LEAD shall obtain and maintain any required QMS approvals and any other approvals, certificates, ratings, licenses, and permits required by the applicable statutory and regulatory requirements. LEAD's QMS shall also address customer and applicable statutory and Authority QMS requirements.

4.4.1.3 The depot's QMS documentation ensures the effective operation and control of LEAD's processes. QMS documented information is designed to meet the requirements of ISO 9001:2015 *and AS9110A*.

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4.4.1.4 The QSM, EMS manual, OH&SMS manual, and the LEAD Strategic Business Plan (Level I) documented information contains the Quality Policy, Environmental Management System (EMS), Occupational Health & Safety Management System (OHSMS), and Quality Objectives, and all other policies relating to the requirements of ISO 9001:2015 *AS9110A*, ISO 14001:2015, and OHSAS 18001:2007.

4.4.1.5 QSPs (Level II) documented information describe how the QMS is implemented, as required by ISO 9001:2015 *and AS9110A*.

4.4.1.6 LEAD Generated/Non-LEAD Generated Technical Documents (Level III) (See QSP 2, Control of Documents) describe how activities affecting quality are performed.

4.4.1.7 Records and retained documented information (Level IV) are identified in QSP 3, Control of Records.

4.4.2 Purpose

4.4.2.1 To establish, document, implement, maintain, and continuously improve a QMS IAW ISO 9001:2015 *and AS9110A* standards.

4.4.2.2 To determine processes needed for the QMS and its applications throughout LEAD along with criteria, methods, sequence and interaction of these processes.

4.4.2.3 To determine inputs required and the outputs expected from these processes;

4.4.2.4 To measure, monitor, and analyze activities used to ensure conformity to specified requirements and attain continuous improvement.

4.4.2.5 To determine the resources needed for these processes and ensure their availability;

4.4.2.6 To assign the responsibilities and authorities for these processes;

4.4.2.7 To address the risks and opportunities as determined for these processes IAW with clause 6.1 of ISO 9001:2015;

4.4.2.8 To evaluate these processes and implement any changes needed to ensure that these processes achieve their intended results;

4.4.2.9 To improve the processes and the QMS.

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4.4.2.10 To establish a mechanism for management to set quality goals and review their attainment.

4.4.2.11 To provide for management review of internal quality audits and completion of corrective action.

4.4.2.12 To determine the need for resources and personnel to maintain the system.

4.4.2.13 To ensure the availability of resources and information necessary to support the operation and monitoring of these processes.

4.4.2.14 To monitor, measure and analyze these processes.

4.4.2.15 To determine the management function responsible for the quality systems and designate, in writing, the appropriate management representatives.

4.4.2.16 To establish quality policies and objectives, ensure the policies are communicated and practiced throughout the organization, and ensure the objectives are routinely met by everyone.

4.4.2.17 To implement actions to achieve planned results and continuous improvement.

4.4.3 LEAD shall maintain documented information to support the operation of its processes and retain documented information to have confidence that the processes are being carried out as planned.

4.5 Documentation Requirements

4.5.1 General

4.5.1.1 The QMS consists of four levels: higher level documents to include QSM and LEAD Strategic Business Plan (SBP), QSPs, LEAD Generated/Non-LEAD Generated Technical Documents, and Quality Records.

4.5.1.2 Commander, LEAD, has developed documented strategic initiatives contained in the LEAD Strategic Business Plan.

4.5.1.3 The QSM establishes the guidelines and overall requirements for the QMS, ISO 9001:2015, and AS9110A standards requirements (For more information see QSP 2). These requirements are applicable to LEAD and its supporting organizations.

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4.5.1.4 The QSPs contain specific guidance as they relate to the QMS. These procedures address what the task is, who is responsible for the performance of the task, and how often the task is performed. QSPs ensure the effective planning, operation and control of QMS processes. QSPs are posted on the depot SharePoint.

4.5.1.5 LEAD Generated/Non-LEAD Generated Technical Documents address how the task is to be performed for individual work processes (See QSP 2).

4.5.1.6 Quality Records provide objective evidence of activities performed and/or results achieved (See QSP 3).

4.5.1.7 LEAD ensures that personnel have access to, and are aware of, relevant QMS documentation and changes.

4.5.2 Quality System Manual (QSM)

4.5.2.1 The Commander delegates the responsibility for the development, preparation, and distribution of the QSM to the QM. LEAD defines its policy for each clause and has a documented procedure that describes each clause.

4.5.2.2 The QSM establishes the structure for all levels of documentation, and the interaction of processes within the QMS.

4.5.2.3 The QSM includes the scope of the QMS and details of and justification for any exclusions.

4.5.2.4 The QM ensures the QSM is current and that all changes are incorporated.

4.5.2.5 The QM reviews "Quality System Controlled" documents to prevent conflicts in policy.

4.5.2.6 The QM ensures that the QSM describes the processes and procedures, as applicable, used for establishing and maintaining proficient personnel, rosters for certifying staff/personnel, training programs, and current approved technical data.

4.5.3 Control of Documents

4.5.3.1 QSPs are established and maintained to control documents and data, i.e., engineering drawings, specifications, organizational procedures, process specifications, WIs, applicable external standards, regulatory documents, etc. Access to electronic data management systems is password protected.

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4.5.3.2 All documented information and data are reviewed for adequacy and approved by authorized personnel prior to issue at the point of use and to prevent the use of invalid or obsolete information (See QSP 2).

4.5.3.3 The QSP for document and data control includes requirements that ensure:

4.5.3.3.1 correct versions of appropriate documents are available at locations of operation;

4.5.3.3.2 obsolete documents are removed or marked "FOR REFERENCE ONLY";

4.5.3.3.3 methods for proper communication and implementation of document changes within the organization are established;

4.5.3.3.4 documents of external origin determined by LEAD to be necessary for the planning and operation of the QMS are identified and their distribution controlled;

4.5.3.3.5 changes to documents are reviewed and approved by the proponent. Revisions/changes, applicable to specific LEAD Generated/Non-LEAD Generated Technical Documents, are noted on the document;

4.5.3.3.6 documents are reviewed and updated as necessary and re-approved. The periodic review of the QSM and QSPs are reviewed and updated on an 18-month interval;

4.5.3.3.7 documents are legible and readily identifiable.

4.5.4 Control of Retained Documented Information - Records

4.5.4.1 QSPs are documented for identification, collection, filing, storage, maintenance, protection, retrieval, retention time, and disposition of pertinent quality records essential to the operation of the QMS (See QSP 3).

4.5.4.2 Quality records are established and maintained to provide objective evidence of conformity to requirements and the effective operation of the QMS. Quality records are legible and identifiable to the product/product components involved and are stored in a protective manner that is readily retrievable. Record retention criteria is defined and documented IAW QSPs, unless otherwise specified by the customer.

4.5.4.3 *A documented procedure is established for controlling records that are created by and/or retained by external providers.*

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INTRANET QUALITY SYSTEM CONTROLLED**5.0 LEADERSHIP AND COMMITMENT****5.1 General Requirements**

The Commander has overall responsibility for quality at LEAD. The Commander implements and continually improves the effectiveness of a documented QMS that involves all activities relating to the quality of products provided to our customers. The QM ensures QSPs are developed to define organizational responsibilities. As required, each functional area shall develop/utilize LEAD Generated/Non-LEAD Generated Technical Documents to ensure all work activities are adequately documented.

5.1.1 Executive leadership shall demonstrate leadership and commitment with respect to the QMS by:

5.1.1.1 taking accountability for the effectiveness of the quality management system;

5.1.1.2 ensuring that the quality policy and quality objectives are established for the QMS and are compatible with the context and strategic direction of the organization;

5.1.1.3 ensuring the integration of the QMS requirements into the organization's business processes;

5.1.1.4 promoting the use of the process approach and risk-based thinking;

5.1.1.5 ensuring that the resources needed for the QMS are available;

5.1.1.6 communicating the importance of effective quality management and of conforming to the QMS requirements;

5.1.1.7 ensuring that the QMS achieves its intended results;

5.1.1.8 engaging, directing and supporting persons to contribute to the effectiveness of the QMS;

5.1.1.9 promoting improvement;

5.1.1.10 supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility.

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INTRANET QUALITY SYSTEM CONTROLLED**5.1.2 Customer Focus**

LEAD's management is committed to providing the best products/services to all of its customers and shall never lose sight of the Soldier in the field. LEAD ensures all customer requirements are determined and met with the aim of enhancing customer satisfaction. LEAD's Management shall ensure that product conformity and on-time delivery performance are measured to enhance customer satisfaction and that appropriate action is taken if planned results are not, or will not be achieved. Each program/contract is reviewed and documented (See QSP 11, Workload Acceptance).

5.1.2.1 Executive leadership shall demonstrate leadership and commitment with respect to customer focus by ensuring that:

5.1.2.1.1 customer and applicable statutory and regulatory requirements are determined, understood and consistently met;

5.1.2.1.2 the risks and opportunities that can affect conformity of products and services and the ability to enhance customer satisfaction are determined and addressed;

5.1.2.1.3 the focus on enhancing customer satisfaction is maintained.

5.2 Quality Policy

5.2.1 Executive Leadership shall establish, implement and maintain a quality policy that:

5.2.1.1 is appropriate to the purpose and context of the organization and supports its strategic direction;

5.2.1.2 provides a framework for setting quality objectives;

5.2.1.3 includes a commitment to satisfy applicable requirements;

5.2.1.4 is committed to provide products and services that meet or exceed customer requirements by continuously measuring, evaluating, and improving our processes for greatest customer satisfaction;

5.2.2 The Commander evaluates the Quality Policy during the Quality Management Review (QMR) to ensure its continuing suitability (See QSP 20, Management Review).

5.2.3 The Quality Policy is disseminated throughout the organization to all personnel to ensure customer requirements are met.

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5.2.4 The Quality Policy provides a framework for establishing and reviewing quality objectives and their understanding within the organization.

5.2.4.1 The quality policy shall:

5.2.4.1.2 be available and be maintained as documented information;

5.2.4.1.3 be communicated, understood and applied within the organization;

5.2.4.1.4 be available to relevant interested parties, as appropriate.

5.3 Organizational roles, responsibilities and authorities

Executive leadership shall ensure that the responsibilities and authorities for relevant roles are assigned, communicated and understood within the organization.

5.3.1 Executive Leadership shall assign the responsibility and authority for:

5.3.1.1 ensuring that the QMS conforms to the requirements;

5.3.1.2 ensuring that the processes are delivering their intended outputs;

5.3.1.3 reporting on the performance of the QMS and on opportunities for improvement (see 10.1), in particular to Executive Leadership;

5.3.1.4 ensuring the promotion of customer focus throughout the organization;

5.3.1.5 ensuring that the integrity of the QMS is maintained when changes to the QMS are planned and implemented.

5.3.2 The Commander has overall responsibility for implementing a QMS involving all activities relating to the quality of products provided to our customers.

5.3.3 The QM has responsibility for providing direction to ensure uniformity of all depot QMS documents.

5.3.4 DPW, Environmental Management office, has responsibility for serving as the Commander's principal staff agent for ISO 14001, Environmental Management System.

5.3.5 The Safety Office Manager has responsibility for serving as the Commander's principal staff agent for OHSAS 18001, Occupational Health and Safety Management Systems.

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5.3.6 Individual directors have responsibility for:

5.3.6.1 ensuring the Quality Policy, quality procedures, and overall commitment are documented and communicated throughout the work force;

5.3.6.2 providing necessary resources;

5.3.6.3 ensuring training and guidance are provided and training records maintained;

5.3.6.4 establishing, maintaining, and reviewing quality procedures to ensure their organizations are in compliance with the QMS;

5.3.6.5 assuring that all maintenance, repair and overhaul activities are carried out IAW LEAD, customer and Authority requirements.

5.3.7 Management Representative

5.3.7.1 The Director of Product Assurance is designated as LEAD's QM and is responsible for reporting performance of the QMS and the need for improvement to the Commander and senior management.

5.3.7.2 The QM is responsible for ensuring processes in the QMS are established, implemented, and maintained.

5.3.7.3 The QM is responsible for ensuring the promotion of awareness of customer requirements throughout the organization.

5.3.7.4 The QM is responsible for ensuring LEAD personnel have unrestricted access to executive leadership to solve quality management issues and other issues related to quality.

5.3.7.5 The QM is the liaison between LEAD and external parties on matters relating to the QMS.

6.0 PLANNING

This clause focuses on planning stages for the QMS and its processes. It addresses the requirements for considering risks and opportunities to ensure quality objectives are met. It also requires that all changes be carried out in a planned manner.

6.1 Actions to address risks and opportunities

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6.1.1 When planning for the QMS, LEAD shall consider internal and external issues and needs and expectations of the interested parties to determine the risk and opportunities that need to be addressed to:

6.1.1.1 give assurance that the quality management system can achieve its intended result(s);

6.1.1.2 enhance desirable effects;

6.1.1.3 prevent, or reduce, undesired effects;

6.1.1.4 achieve improvement.

6.1.2 LEAD shall plan:

6.1.2.1 actions to address these risks and opportunities;

6.1.2.1 how to integrate and implement the actions into its quality management system processes;

6.1.2.2 how to evaluate the effectiveness of these actions.

6.1.3 Actions taken to address risks and opportunities shall be proportionate to the potential impact on the conformity of products and services.

6.1.4 Risk Management

6.1.4.1 QSP 24 – Risk Management establishes implements and maintains a process for managing risk in order to achieve applicable requirements that includes:

6.1.4.1.1 assignment of responsibility for risk management;

6.1.4.1.2 defining risk and its risk criteria (e.g., likelihood, consequences, risk acceptance);

6.1.4.1.3 identification, assessment and communication of risks throughout product realization;

6.1.4.1.4 identification, implementation and management of actions to mitigate risks that exceed the defined risk acceptance criteria;

6.1.4.1.5 acceptance of risk remaining after implementation of mitigating actions.

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INTRANET QUALITY SYSTEM CONTROLLED**6.2 Quality objectives and planning to achieve them**

6.2.1 LEAD shall establish quality objectives at relevant functions, levels and processes needed for the QMS. LEAD's Quality Objectives are stated and established throughout the depot in Strategic Business Plan document and are posted on the LEAD SharePoint. The Quality Objectives shall be measurable and consistent with the Quality Policy.

6.2.2 The quality objectives shall:

6.2.2.1 be consistent with the quality policy;

6.2.2.2 be measurable;

6.2.2.3 take into account applicable requirements;

6.2.2.4 be relevant to conformity of products and services and to enhancement of customer satisfaction;

6.2.2.5 be monitored;

6.2.2.6 be communicated;

6.2.2.7 be updated as appropriate.

6.2.3 The organization shall maintain documented information on the quality objectives.

6.2.4 When planning how to achieve its quality objectives, LEAD shall determine:

6.2.4.1 what will be done;

6.2.4.2 what resources will be required;

6.2.4.3 who will be responsible;

6.2.4.4 when it will be completed;

6.2.4.5 how the results will be evaluated.

6.2.5 QMS Planning

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6.2.5.1 Each functional activity coordinating the acceptance of workload performs and documents quality planning. All programs/contracts are reviewed to identify how quality requirements will be met.

6.2.5.2 Executive leadership shall ensure:

6.2.5.2.1 planning of the QMS is carried out in order to meet the requirements of the QMS and Quality Objectives;

6.2.5.2.2 appropriate considerations are given to maintaining the integrity of the QMS when changes to the QMS are planned, developed, and implemented and that applicable quality records are maintained to ensure customer expectations are met.

6.2.5.2.3 the safety objectives including those needed to meet customer requirements for product are established and communicated at relevant functions.

6.2.5.2.4 The QM ensures that changes are implemented in a controlled manner to ensure that the integrity of the QMS is maintained (See QSP 2), and that recommended changes to the QMS are reviewed during QMR meetings (See QSP 20).

6.3 Planning of changes

When the organization determines the need for changes to the quality management system, the changes shall be carried out in a planned manner.

6.3.1 LEAD shall consider:

6.3.1.1 the purpose of the changes and their potential consequences;

6.3.1.2 the integrity of the quality management system;

6.3.1.3 the availability of resources;

6.3.1.4 the allocation or reallocation of responsibilities and authorities.

7.0 SUPPORT

7.1 Resources

LEAD shall determine and provide the resources needed for the establishment, implementation, maintenance and continual improvement of the QMS.

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7.1.1 LEAD shall consider:

7.1.1.1 the capabilities of, and constraints on, existing internal resources;

7.1.1.2 what needs to be obtained from external providers.

7.1.2 Provision of Resources

7.1.2.1 The Commander and senior management are responsible for ensuring:

7.1.2.1.1 adequate resources are available to implement and maintain the QMS and continually improve their effectiveness. This includes providing training and guidance to implement a successful QMS to enhance customer satisfaction by meeting requirements;

7.1.2.1.2 continual evaluation and assessment of tools, technical data and necessary qualified personnel to ensure the safe completion of the maintenance, repair, and overhaul activities.

7.1.3 People

LEAD shall determine and provide the persons necessary for the effective implementation of its quality management system and for the operation and control of its processes.

7.1.3 Infrastructure

7.1.3.1 LEAD shall:

7.1.3.1.1 determine, provide and maintain the infrastructure needed for the operation of its processes and to achieve conformity to product and service requirements (See QSP 12, Customer Property, QSP 13, Process Control, QSP 18, Infrastructure/Work Environment). The infrastructure includes buildings, workspaces, utilities, process equipment (hardware and software), transportation, information and communication technology, and supporting services;

7.1.3.1.2 *determine, provide and maintain facilities for maintenance, repair, and overhaul services acceptable to applicable customers and authorities away from its fixed location;*

7.1.3.1.3 allocate resources to maintain the depot's infrastructure.

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INTRANET QUALITY SYSTEM CONTROLLED**7.1.4 Environment for the operation of processes**

LEAD shall determine, provide and maintain the environment necessary for the operation of its processes and to achieve conformity of products and services. (See QSP 18).

7.1.5 Monitoring and Measuring Resources**7.1.5.1 General**

LEAD shall determine and provide the resources needed to ensure valid and reliable results when monitoring or measuring is used to verify the conformity of products and services to requirements.

LEAD shall ensure that the resources provided:

7.1.5.1.1 are suitable for the specific type of monitoring and measurement activities being undertaken;

7.1.5.1.2 are maintained to ensure their continuing fitness for their purpose.

7.1.5.1.3 LEAD shall retain appropriate documented information as evidence of fitness for purpose of the monitoring and measurement resources.

7.1.5.2 Measurement Traceability

LEAD controls and maintains calibration of TMDE resources capable of demonstrating product conformance to specified requirements. Utilization of equipment, whether owned, rented/leased, or customer provided, is consistent with required measurement criteria. TRMD maintains a USATA inspected lab for Missile Specific material. The TMDE Group under U.S. Army Aviation and Missile Command (AMCOM) of Huntsville, Alabama, is the primary agency responsible for calibration. AMCOM maintains a calibration program traceable to recognized National Institute of Standards and Technology (NIST) standards.

7.1.5.3 Each piece of TMDE resource is calibrated and/or documented on the Instrument Master Record File (IMRF), maintained by the TMDE Support Manager (TSM). This ensures the control, calibration, and maintenance of TMDE resources to:

7.1.5.3.1 identify measurement and accuracy requirements;

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7.1.5.3.2 select the equipment capable of performing these measurements and maintain a register of TMDE resources and define the processes employed in their calibration/verification including details of equipment type, unique identification, location, frequency of checks, check methods and acceptance criteria;

7.1.5.3.3 identify calibration standards and prescribed intervals;

7.1.5.3.4 establish, document, and maintain calibration procedures (See QSP 7);

7.1.5.3.5 indicate calibration status of identified monitoring and measuring resources by approved labels, tags, or other approved methods;

7.1.5.3.6 maintain calibration results and verification records for identified monitoring and measuring resources;

7.1.5.3.7 establish, implement and maintain a process for the recall of monitoring and measuring resources requiring calibration or verification;

7.1.5.3.8 assess and document the validity of prior test(s) if calibration expires or if TMDE is found to be out of calibration;

7.1.5.3.9 ensure environmental conditions are suitable for calibration, inspection, and measurement;

7.1.5.3.10 ensure adequate handling and storage of monitoring and measuring resources;

7.1.5.3.11 safeguard facilities, hardware, and software calibration integrity;

7.1.5.3.12 ensure computer software ability to satisfy intended application;

7.1.5.3.13 ensure test hardware and software, automated test equipment and plotters used to produce inspection data, personally owned and customer supplied equipment are checked and verified at prescribed intervals to prove capability of verifying product acceptance IAW documented QSPs.

7.1.6 Organizational knowledge

LEAD shall determine the knowledge necessary for the operation of its processes and to achieve conformity of products and services. This knowledge shall be maintained and be made available to the extent necessary. When addressing changing needs and

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trends, the organization shall consider its current knowledge and determine how to acquire or access any necessary additional knowledge and required updates.

7.2 Competence

7.2.1 LEAD shall:

7.2.1.1 determine and provide the persons necessary for the effective implementation of its QMS and for the operation and control of its processes. LEAD assigns personnel to duties in support of the QMS based on their level of education, training, skills, and experience documented in their respective personnel and training records.

7.2.1.2 determine the necessary competence of person(s) doing work under its control that affects the performance and effectiveness of the QMS;

7.2.1.3 ensure that these persons are competent on the basis of appropriate education, training, or experience;

7.2.1.4 where applicable, take actions to acquire the necessary competence, and evaluate the effectiveness of the actions taken;

7.2.2 Procedures are established and maintained that specify the requirement to identify training needs and ensure personnel are properly trained and qualified to perform their assigned task(s) and that personnel performing specifically assigned tasks are qualified to do so on the basis of appropriate education, training, and experience. Training is projected, scheduled, and recorded to ensure organizational and individual needs can be met without compromising organizational efficiency.

7.2.3 Evaluate the effectiveness of this process.

7.2.4 When required, special qualifications and/or certification training is provided to personnel performing *specific* work affecting conformity to product requirements, specifications, and statutory and regulatory requirements. Quality records are maintained to provide evidence of qualification, training, and experience.

7.2.5 *Personnel performing maintenance, repair, and overhaul services and release of articles are qualified and certified IAW Authority and customer requirements.*

7.2.6 *Initial and recurrent training programs are established to ensure the personnel performing specific tasks remain current in terms of procedure, human factors, technical knowledge and applicable Authority requirements.*

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7.2.7 Training is provided that covers changes in the relevant Authority requirements and internal and external standards for maintenance, repair, and overhaul services.

7.2.8 Retain appropriate documented information as evidence of competence.

7.3 Awareness

LEAD shall ensure that persons doing work under the organization's control are aware of:

7.3.1 the quality policy;

7.3.2 relevant quality objectives;

7.3.3 their contribution to the effectiveness of the quality management system, including the benefits of improved performance;

7.3.4 the implications of not conforming with the quality management system requirements.

7.4 Communication

LEAD shall determine the internal and external communications relevant to the QMS, including:

7.4.1 on what it will communicate;

7.4.2 when to communicate;

7.4.3 with whom to communicate;

7.4.4 how to communicate;

7.4.5 who communicates.

7.4.6 All matters relevant to the effectiveness of the QMS shall be communicated electronically or by hard copy to the affected organization.

7.5 Documented information

7.5.1 General

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7.5.1.1 LEAD's quality management system shall include:

7.5.1.1.1 documented information required by this International Standard;

7.5.1.1.2 documented information determined by the organization as being necessary for the effectiveness of the quality management system.

7.5.1.2 The QMS consists of four levels: QSM, QSPs, LEAD Generated/Non-LEAD Generated Technical Documents, and Quality Records.

7.5.1.3 Commander, LEAD, has developed documented strategic initiatives contained in the depot Strategic Plan.

7.5.1.4 The QSM establishes the guidelines and overall requirements for the QMS, ISO 9001:2008, and AS9110A standards requirements. These requirements are applicable to LEAD and its supporting organizations.

7.5.1.5 The QSPs contain specific guidance as they relate to the QMS. These procedures address what the task is, who is responsible for the performance of the task, and how often the task is performed. QSPs ensure the effective planning, operation and control of QMS processes. QSPs are posted on the depot SharePoint.

7.5.1.6 LEAD Generated/Non-LEAD Generated Technical Documents address how the task is to be performed for individual work processes (See QSP 2).

7.5.1.7 Quality Records provide objective evidence of activities performed and/or results achieved (See QSP 3).

7.5.1.8 LEAD ensures that personnel have access to, and are aware of, relevant QMS documentation and changes.

7.5.2 Creating and updating

7.5.2.1 When creating and updating documented information, the organization shall ensure appropriate:

7.5.2.1.1 identification and description (e.g. a title, date, author, or reference number);

7.5.2.1.2 format (e.g. language, software version, graphics) and media (e.g. paper, electronic);

7.5.2.1.3 review and approval for suitability and adequacy.

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7.5.3 Control of Maintained Documented Information

7.5.3.1 Documented information required by the quality management system and by ISO 9001-2015 International Standard shall be controlled to ensure:

7.5.3.1.1 it is available and suitable for use, where and when it is needed;

7.5.3.1.2 it is adequately protected (e.g. from loss of confidentiality, improper use, or loss of integrity).

7.5.3.2 For the control of documented information, LEAD shall address the following activities, as applicable:

7.5.3.2.1 distribution, access, retrieval and use;

7.5.3.2.2 storage and preservation, including preservation of legibility;

7.5.3.2.3 control of changes (e.g. version control);

7.5.3.2.4 retention and disposition.

7.5.3.3 Documented information of external origin determined by LEAD to be necessary for the planning and operation of the quality management system shall be identified as appropriate, and be controlled.

7.5.3.4 Documented information retained as evidence of conformity shall be protected from unintended alterations.

7.5.3.5 QSPs are established and maintained as control documents and data, along with engineering drawings, specifications, organizational procedures, process specifications, WIs, applicable external standards, regulatory documents, etc. Access to electronic data management systems is password protected.

7.5.3.6 Documents and data are reviewed for adequacy and approved by authorized personnel prior to issue at the point of use and to prevent the use of invalid or obsolete information (See QSP 2).

7.5.3.7 The QSP for document and data control includes requirements that ensure:

7.5.3.7.1 correct versions of appropriate documents are available at locations of operation;

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7.5.3.7.2 obsolete documents are removed or marked "FOR REFERENCE ONLY";

7.5.3.7.3 methods for proper communication and implementation of document changes within LEAD are established;

7.5.3.7.4 documents of external origin determined by LEAD to be necessary for the planning and operation of the QMS are identified and their distribution controlled;

7.5.3.7.5 changes to documents are reviewed and approved by the proponent. Revisions/changes, applicable to specific LEAD Generated/Non-LEAD Generated Technical Documents, are noted on the document;

7.5.3.7.6 documents are reviewed and updated as necessary and re-approved. The periodic review of the QSM and QSPs are reviewed and updated on an 18-month interval;

7.5.3.7.7 documents are legible and readily identifiable.

7.5.4 Control of Retained Documented Information/Records

7.5.4.1 QSPs are documented for identification, collection, filing, storage, maintenance, protection, retrieval, retention time, and disposition of pertinent quality records essential to the operation of the QMS (See QSP 3).

7.5.4.2 Quality records are established and maintained to provide objective evidence of conformity to requirements and the effective operation of the QMS. Quality records are legible and identifiable to the product/product components involved and are stored in a protective manner that is readily retrievable. Record retention criteria is defined and documented IAW QSPs, unless otherwise specified by the customer.

7.5.4.3 *A documented procedure is established for controlling records that are created by and/or retained by external providers.*

8.0 OPERATION

8.1 Operational planning and control

8.1.1 LEAD shall plan, implement and control the processes (see 4.4) needed to meet the requirements for the provision of products and services, and to implement the actions determined in Clause 6, by:

8.1.1.1 determining the requirements for the products and services;

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8.1.1.2 establishing criteria for the processes and the acceptance of products and services;

8.1.1.3 determining the resources needed to achieve conformity to the product and service requirements;

8.1.1.4 implementing control of the processes in accordance with the criteria;

8.1.1.5 determining, maintaining and retaining documented information to the extent necessary to have confidence that the processes have been carried out as planned; and to demonstrate the conformity of products and services to their requirements.

8.1.2 The output of this planning shall be suitable for the LEAD's operations.

8.1.3 LEAD shall control planned changes and review the consequences of unintended changes, taking action to mitigate any adverse effects, as necessary.

8.1.4 LEAD shall ensure that outsourced processes are controlled (see 8.4).

8.1.5 Planning of Product Realization

8.1.5.1 LEAD shall determine the following, as appropriate, in the Planning of product realization process:

8.1.5.1.1 LEAD shall plan and develop the processes needed for product realization. This shall be consistent with the requirements of other processes of the QMS;

8.1.5.1.2 LEAD shall review all technical documentation for each new program it is considering for acceptance. The review identifies the specific quality objectives and requirements for the product, the need to establish processes and documents, and resources and facilities required for each program;

8.1.5.1.3 LEAD shall also determine customer requirements and quality objectives of the product to be incorporated into the Quality Data Pack (QDP), as applicable;

8.1.5.1.4 *product requirements include considerations of aspects such as product and personal safety, reliability, availability and maintainability, producibility and inspectability, suitability of parts and materials, Foreign Object Damage (FOD), selection and development of embedded software, and recycling or final disposal of the product at the end of its life;*

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8.1.5.1.5 other documentation and processes that are specific to the product and need to be implemented before the beginning of each new program shall be reviewed and established;

8.1.5.1.6 required verification, validation, monitoring, measurement, and inspection and test activities specific to the product realization process shall be established and records maintained;

8.1.5.1.7 all required workload acceptance criteria, including the records needed to provide evidence that the realization process and resulting product meet requirements, is contained in QSP 11;

8.1.5.1.8 identify the resources needed to support operation and maintenance of the product.

8.1.6 Project Management

8.1.6.1 *LEAD shall plan and manage product realization in a structured and controlled manner to meet requirements at acceptable risk, within resource and schedule constraints.*

8.1.7 Configuration Management

8.1.7.1 *LEAD shall establish, implement and maintain a configuration management process that includes, as appropriate, to the product/workload:*

8.1.7.1.1 *configuration management planning for each workload;*

8.1.7.1.2 *configuration identification;*

8.1.7.1.3 *change control;*

8.1.7.1.4 *configuration status accounting; and*

8.1.7.1.5 *configuration audit.*

8.1.8 Control of Work Transfers

8.1.8.1 LEAD shall establish, implement and maintain a process to plan and control the temporary or permanent transfer of work (e.g., from one facility to another, from LEAD to an external provider, from one external provider to another external provider) and to verify the conformity of work to requirements.

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8.2 Requirements for Products and Services

8.2.1 Customer Communication

LEAD maintains an effective method of communicating with the customer in relation to customer requirements of product, amendments to programs, and customer feedback including customer complaints. (See QSP 8, Customer Satisfaction, QSP 17 and QSP 20). Communication with customers shall include:

8.2.1.1 providing information relating to products and services;

8.2.1.2 handling enquiries, contracts or orders, including changes;

8.2.1.3 obtaining customer feedback relating to products and services, including customer complaints;

8.2.1.4 handling or controlling customer property;

8.2.1.5 establishing specific requirements for contingency actions, when relevant.

8.2.2 Determining the requirements for products and services

LEAD is a designated DOD maintenance, overhaul, and repair and missile recertification facility and receives requests for cost estimates from various sources. LEAD receives programs grouped into 3 general categories, i.e., new workload, enhanced existing workload, and additional existing workload. LEAD's role is to ensure customer requirements are understood in all three categories, any differences in requirements are resolved, and the necessary resources to complete any/all programs accepted are provided. When determining the requirements for the products and services to be offered to customers, LEAD shall ensure that:

8.2.2.1 the requirements for the products and services are defined, including any applicable statutory and regulatory requirements and those considered necessary by LEAD;

8.2.2.2 LEAD can meet the claims for the products and services it offers.

8.2.2.3 all customer specified requirements, including requirements for delivery and post-delivery activities can be met;

8.2.2.4 requirements not stated by the customer, but necessary for specified and intended use of the product are met;

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8.2.2.5 statutory and regulatory requirements and other special requirements considered necessary by LEAD are met.

8.2.2.6 Quality planning is conducted prior to the initiation of any/all programs.

8.2.3 Review of the requirements for products and services

8.2.3.1 LEAD shall ensure that it has the ability to meet the requirements for products and services to be offered to customers. LEAD shall review product related requirements prior to the commitment to supply products to the customer by ensuring:

8.2.3.1.1 product, contract, or order requirements are defined and resolved and LEAD is able to meet those requirements;

8.2.3.1.2 product, contract, or order requirements differing from those previously expressed are resolved and LEAD is able to meet those requirements;

8.2.3.1.3 contractual requirements are reviewed so that special requirements of product are determined (e.g., scope of work, technical data, delivery requirements, and requirements regarding subcontracting of work);

8.2.3.1.4 the evaluation and review of all risks related to such things as new and developing technology or short lead-times;

8.2.3.1.5 retain documented information, as applicable on the results of the review and on any new requirements for the products and services;

8.2.3.1.6 maintain documented information and records are maintained from the results of the review and actions taken;

8.2.3.1.7 the customer requirements including the requirements for delivery and post-delivery activities are confirmed even if no documented statement of requirement is provided by the customer;

8.2.3.1.8 relevant documents are amended and relevant personnel are aware of changes in the customer requirements if in fact those requirements have changed.

8.2.3.2 Solicitation of new workload is the primary responsibility of the BDO, (See QSP 11).

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8.2.3.3 In addition to new workload, LEAD also receives programs that require modifications/enhancements to existing programs. These programs are coordinated by the functional activity that accepts the work.

8.2.3.4 LEAD also receives programs for additional quantities of existing programs. Customer requirements have not changed; therefore, pre-production planning functions are not required.

8.2.3.5 *LEAD performed risk analysis on all new work loads and programs requiring new technologies, short delivery time, or special processes.*

8.2.3.6 Each new program/contract is reviewed using AMLD Form 3800, Planning Review Document.

8.2.4 Changes to requirements for products and services

LEAD shall ensure that relevant documented information is amended, and that relevant persons are made aware of the changed requirements, when the requirements for products and services are changed.

8.3 Design and Development

Not applicable to LEAD. Product design and control is the responsibility of the customer. The Original Equipment Manufacturer (OEM) or the customer performs all design and development activity.

8.4 Control of externally provided processes, products and services

8.4.1 General

LEAD shall ensure that externally provided processes, products and services conform to requirements. LEAD shall determine the controls to be applied to externally provided processes, products and services when:

8.4.1.1 products and services from external providers are intended for incorporation into LEAD's own products and services;

8.4.1.2 products and services are provided directly to the customer(s) by external providers on behalf of LEAD;

8.4.1.3 a process, or part of a process, is provided by an external provider as a result of a decision by LEAD.

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LEAD shall determine and apply criteria for the evaluation, selection, monitoring of performance, and re-evaluation of external providers, based on their ability to provide processes or products and services in accordance with requirements. LEAD shall retain documented information of these activities and any necessary actions arising from the evaluations.

8.4.1.4 Purchasing Process

8.4.1.4.1 LEAD is responsible for the conformity of all products purchased from external providers, including product from sources identified by the customer.

8.4.1.4.2 QSPs are maintained to ensure externally provided products and services conform to specified requirements while meeting regulatory, and legal requirements. The ACC has primary responsibility and authority to implement a purchasing system, measure its effectiveness, and provide feedback for the QMR (See QSP 19, Purchasing).

8.4.1.4.3 LEAD's external providers are evaluated and selected based on their ability to meet contract requirements, including customer identified external providers. Criteria for selection, evaluation, and re-evaluation shall be established. Records of the results of the evaluation and resulting actions taken shall be maintained.

8.4.1.4.4 On-site evaluations of external providers are conducted, as required, to assess manufacturing capabilities and quality system activities.

8.4.1.4.5 Quality records of LEAD's external providers' performance are maintained.

8.4.1.4.6 Record and maintain results of evaluations and re-evaluations of external providers and follow-up actions necessary when dealing with external providers that do not meet requirements.

8.4.2 Type and extent of control

LEAD shall ensure that externally provided processes, products and services do not adversely affect LEAD's ability to consistently deliver conforming products and services to its customers. LEAD shall:

8.4.2.1 ensure that externally provided processes remain within the control of its QMS;

8.4.2.2 define both the controls that it intends to apply to an external provider and those it intends to apply to the resulting output;

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8.4.2.3 take into consideration

8.4.2.3.1 the potential impact of the externally provided processes, products and services on the LEAD's ability to consistently meet customer and applicable statutory and regulatory requirements;

8.4.2.3.2 the effectiveness of the controls applied by the external provider;

8.4.2.3.3 determine the verification, or other activities, necessary to ensure that the externally provided processes, products and services meet requirements.

8.4.2.4 Outsourced Processes

8.4.2.4.1 *LEAD shall establish, implement, and maintain a process to plan and control any product or processes outsourced or performed by an external party.*

8.4.2.4.2 LEAD shall evaluate the degree to which control can be maintained and the potential input on meeting customer requirements.

8.4.2.4.3 The type and extent of customer control will be determined based on achieving necessary outcome.

8.4.2.4.4 LEAD shall verify the conformity of work outsourced or performed by an external party.

8.4.2.5 Responsibilities

8.4.2.5.1 DPA is responsible for monitoring, controlling, implementation, and modification of this section and will take necessary action accordingly.

8.4.3 Information for external providers

8.4.3.1 LEAD shall ensure the adequacy of requirements prior to their communication to the external provider. LEAD shall communicate to external providers its requirements for:

8.4.3.1.1 the processes, products and services to be provided;

8.4.3.1.2 the approval of:

8.4.3.1.2.1 products and services;

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8.4.3.1.2.2 methods, processes and equipment;

8.4.3.1.2.3 the release of products and services;

8.4.3.1.2.4 competence, including any required qualification of persons;

8.4.3.1.2.5 the external providers' interactions with the organization;

8.4.3.1.2.6 control and monitoring of the external providers' performance to be applied by LEAD;

8.4.3.1.3 verification or validation activities that LEAD, or its customer, intends to perform at the external providers' premises.

8.4.3.2 Purchasing Information

8.4.3.2.1 Directorates supply necessary product, procedure, process and equipment requirements, i.e., drawings, type, class, style, grade, or other identification to purchasing. These requirements are communicated to the external providers and clearly stated on purchase documents.

8.4.3.2.2 Other purchasing information supplied by directorates may include:

8.4.3.2.2.1 QMS requirements, personnel qualifications, and requirements for approval of products, procedures, processes, and equipment, as needed;

8.4.3.2.2.2 related information to ensure externally provided products and services conform to specified requirements;

8.4.3.2.2.3 identification and revision status of specifications, drawings, process requirements, inspection/verification instructions and other relevant technical data;

8.4.3.2.2.4 requirements for test, inspection, verification (including maintenance process verification), use of statistical techniques for product acceptance, and related instructions for acceptance by the organization, and, as applicable, critical items including key characteristics;

8.4.3.2.2.5 requirements for test specimens (e.g., production method, number, storage conditions) for design approval, inspection/verification, investigation or auditing;

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8.4.3.2.2.6 requirements regarding the need for external provider to notify LEAD of nonconforming product and arrangements for making arrangements for obtaining LEAD or customer's approval for nonconforming product disposition;

8.4.3.2.2.7 requirements regarding the need for external provider to notify LEAD of changes in product and/or process definition and, where required, obtain organization approval, when required.

8.4.3.3 Verification of Externally Provided Products and Services

8.4.3.3.1 Verification that externally provided products and services meet specified requirements is accomplished at LEAD or, when deemed necessary, at the contractor's facility.

A process is established to resolve disputes or non-compliances.

8.4.3.3.2 Incoming material or product is not used or processed until it has been inspected or otherwise verified as conforming to specified contractual requirements.

8.4.3.3.3 Where externally provided products and services is released for maintenance use pending completion of all required verification activities, it shall be identified and recorded to allow recall and replacement if it is subsequently found that the product does not meet requirements.

8.4.3.3.4 Where the verification/inspection activities have been delegated to external provider, the requirement for delegation is clearly defined and a register/log of delegations is maintained. This does not absolve LEAD of its responsibility to provide acceptable product and ensure compliance with all requirements.

8.4.3.3.5 Where LEAD or its customer intend to perform verification at the external provider's premises, the organization shall state the intended verification arrangements and method of product release in the purchasing information.

8.5 Production and service provision

8.5.1 Control of Production and Service Provision

8.5.1.1 LEAD shall plan and carry out production and service provisions under controlled conditions, which shall include:

8.5.1.1.1 the availability of information describing characteristics of the product and customer requirements;

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8.5.1.1.2 the use of suitable processes and equipment including accurate WIs;

8.5.1.1.3 the availability and use of suitable TMDE resources;

8.5.1.1.4 the implementation of monitoring and measurement activities at appropriate stages to verify that criteria for control of processes or outputs, and acceptance criteria for products and services, have been met;

8.5.1.1.5 the use of suitable infrastructure and environment for the operation of processes;

8.5.1.1.6 the appointment of competent persons, including any required qualification;

8.5.1.1.7 the validation, and periodic revalidation, of the ability to achieve planned results of the processes for production and service provision, where the resulting output cannot be verified by subsequent monitoring or measurement;

8.5.1.1.8 the implementation of actions to prevent human error;

8.5.1.1.9 the implementation of release, delivery and post-delivery activities.

8.5.1.2 Procedures are established to ensure the availability of program requirements, WIs, equipment, drawings, part lists, material and process specifications, monitoring and measuring resources, and the implementation of all activities, such as auditing, monitoring and measurement, etc., (See QSP 7, Control of monitoring and measuring resources, QSP 11, and QSP 13).

8.5.1.3 Procedures are written and established for handling, storing, packaging, preserving, release, delivery, and post-delivery of material in a safe manner that prevents damage or deterioration (See QSP 5, Control of Nonconforming Product, QSP 12, and QSP 16, Servicing).

8.5.1.4 Customer support is provided by developing equipment manuals, on-site training, replacement part support, technical support, servicing, and maintenance. QSPs are established and maintained for performing product servicing and verifying that specified contract/program requirements have been met. Quality records of servicing and verification of results are maintained.

8.5.1.5 *Planning of the production, maintenance/repair operation shall be considered as appropriate:*

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8.5.1.5.1 establishing, implementing and maintaining appropriate processes to manage critical items, including process controls where key characteristics have been identified;

8.5.1.5.2 manufacturing and using tooling to measure variable data;

8.5.1.5.3 identifying in-process inspection/verification points when adequate verification of conformance cannot be performed at later stages of realization;

8.5.1.5.4 establishing, implementing and maintaining special processes.

8.5.1.6 Maintenance Process Verification

8.5.1.6.1 New maintenance processes shall be documented, qualified and approved by the customer and/or Authority to ensure their capability of performing the maintenance and repair in compliance with established requirements.

8.5.1.7 Control of Maintenance Process Changes

8.5.1.7.1 Personnel authorized to approve changes to maintenance processes shall be identified.

8.5.1.7.2 LEAD shall control and document changes affecting processes, maintenance equipment, tools or software programs.

8.5.1.7.3 The result of changes to maintenance processes shall be assessed to confirm that the desired effect has been achieved without adverse effects on product conformity.

8.5.1.8 Control of Maintenance Equipment, Tools and Programs

8.5.1.8.1 Maintenance equipment, tools and programs used to automate and control/monitor product realization processes shall be those defined by the technical data or demonstrated as equivalent, prior to use.

8.5.1.8.2 Maintenance equipment, tools and programs shall be maintained and inspected periodically.

8.5.1.8.3 Storage requirements, including periodic preservation/condition checks, shall be defined for maintenance equipment or tooling in storage.

8.5.1.9 Validation of Processes for Production and Service Provision

8.5.1.9.1 Processes that affect the quality of the product/service have QSPs established to ensure consistent performance. These procedures are posted on the depot

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SharePoint. All processes, which include processes where the resulting output cannot be verified by subsequent monitoring and measurement activities, may be referred to as special processes, are conducted under controlled conditions at all times. Controlled conditions include control of raw material, equipment, processes, personnel, and environment. All personnel are responsible for ensuring only current WIs and specifications are used.

8.5.1.9.2 Processes are controlled, validated by a documented procedure ensuring conformance to specified requirements and planned results. WIs are required in any area where lack of instruction would affect an individual's ability to produce the desired result. WIs are intended to supplement the use of technical data, i.e., DMWRS, TMs, LOs, MWOs, SOWs, PMF manuals, TRMF manuals, etc. Special customer requirements are controlled and documented as specified in the QSPs.

8.5.1.9.3 Processes are monitored to ensure continued acceptability and compliance with published standards, codes, and regulations. Where applicable, statistical process control (SPC) techniques are used to monitor process parameters and product characteristics. DPA continuously monitors the effectiveness of process controls and changes to the process through the internal quality audit program. Manufacturing processes, equipment, fixtures, tooling, templates, and software are evaluated for acceptability through first-piece verification of parts produced and records are maintained. Required maintenance of equipment is conducted through a planned scheduled maintenance program to ensure continued process capability.

8.5.1.9.4 Personnel receive training for special processes, i.e., Electrostatic Discharge (ESD), welding, soldering, Non-Destructive Testing (NDT), etc., and operating systems, to effectively accomplish work responsibilities.

8.5.1.9.5 Pre-production planning is accomplished to ensure process controls are established prior to start-up of the program.

8.5.1.9.6 The area supervisor maintains individual certification records.

8.5.1.9.7 The Contracting Officer's Representative (COR) maintains records of newly procured equipment.

8.5.2 Identification and Traceability

LEAD shall use suitable means to identify outputs when it is necessary to ensure the conformity of products and services and shall identify the status of outputs with respect to monitoring and measurement requirements throughout production and service provision. LEAD shall control the unique identification of the outputs when traceability is

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a requirement, and shall retain the documented information necessary to enable traceability.

8.5.2.1 QSPs are established that identify the product/service in all stages from initial receipt/induction through final production (See QSP 9, Identification and Traceability (Tagging)).

8.5.2.2 If traceability is required by the customer, QSPs are established for unique and suitability identification of individual products/services or batches/lots throughout product realization (See QSP 12).

8.5.2.3 Unique identification/traceability records, i.e., shop tags, condition code tags/labels, test data sheets, quality records, certificates of conformance, etc., are maintained, as required by the customer and records are maintained.

8.5.3 Property belonging to customers or external providers

LEAD shall exercise care with property belonging to customers or external providers while it is under LEAD's control or being used by LEAD and shall identify, verify, protect and safeguard customers' or external providers' property provided for use or incorporation into the products and services. When the property of a customer or external provider is lost, damaged or otherwise found to be unsuitable for use, LEAD shall report this to the customer or external provider and retain documented information on what has occurred.

8.5.3.1 QSPs which provide for verification, inventory, security, storage, maintenance, and the reporting of customer-supplied products to include intellectual property and personal data while at LEAD's facility shall be maintained (See QSP 12).

8.5.3.2 QSPs ensure control of customer-supplied products by specifying:

8.5.3.2.1 examination of product upon receipt for damage or deterioration;

8.5.3.2.2 performance of periodic inspections to determine serviceability;

8.5.3.2.3 identification of safeguards to prevent unauthorized use or improper disposal.

8.5.3.3 Receipt, storage, identification, and inspection records of customer-supplied products are maintained. Problems associated with customer-supplied product, including lost or stolen product, are recorded and reported to the customer for further action.

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INTRANET QUALITY SYSTEM CONTROLLED**8.5.4 Preservation**

8.5.4.1 LEAD shall preserve the outputs during production and service provision, to the extent necessary to ensure conformity to requirements. LEAD establishes and implements documented procedures for the preservation of product, to include handling, cleaning, marking and labeling, storage, shelf life control and stock rotation, special handling for Hazardous Material (HAZMAT) and other sensitive product, packaging, protection, and delivery of materials and products. Procedures are implemented from the point of receipt/fabrication through storage and continue to final destination IAW applicable statutory and regulatory requirements. When required, LEAD establishes and implements prevention, detection, and removal of foreign objects.

8.5.4.2 Controlled storage areas are provided to prevent damage and/or deterioration of materials and products. Procedures are established for packing and marking to ensure protection and identification (See QSP 9 and QSP 12).

8.5.4.3 To prevent unintended use, items intended for maintenance use shall be segregated from items not intended for maintenance.

8.5.5 Post-Delivery Activities

LEAD shall meet requirements for post-delivery activities associated with the products and services. In determining the extent of post-delivery activities that are required, LEAD shall consider:

8.5.5.1 statutory and regulatory requirements;

8.5.5.2 the potential undesired consequences associated with its products and services;

8.5.5.3 the nature, use and intended lifetime of its products and services;

8.5.5.4 customer requirements;

8.5.5.5 customer feedback.

8.5.5.6 *collection and analysis of in-service data;*

8.5.5.7 *actions to be taken, including investigation and reporting, when problems are detected after delivery;*

8.5.5.8 *control and updating of technical data;*

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8.5.5.9 *approval, control and use of repair schemes;*

8.5.5.10 *controls required for off-site work (e.g., work undertaken at customer's facility or location).*

8.5.6 Control of changes

LEAD shall review and control changes for production or service provision, to the extent necessary to ensure continuing conformity with requirements and shall retain documented information describing the results of the review of changes, the person(s) authorizing the change, and any necessary actions arising from the review.

8.6 Release of products and services

LEAD shall implement planned arrangements, at appropriate stages, to verify that the product and service requirements have been met. The release of products and services to the customer shall not proceed until the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority and, as applicable, by the customer.

8.6.1 LEAD shall retain documented information on the release of products and services. The documented information shall include:

8.6.1.1 evidence of conformity with the acceptance criteria;

8.6.1.2 traceability to the person(s) authorizing the release.

8.7 Control of nonconforming outputs

8.7.1 LEAD shall ensure that outputs that do not conform to their requirements are identified and controlled to prevent their unintended use or delivery and shall take appropriate action based on the nature of the nonconformity and its effect on the conformity of products and services. This shall also apply to nonconforming products and services detected after delivery of products, during or after the provision of services.

8.7.1.1 QSPs are established and maintained to ensure nonconforming material is identified and controlled to prevent unintended use or delivery. Nonconforming products are identified, documented, and segregated in holding areas until disposition is determined (See QSP 5).

8.7.1.2 LEAD shall deal with nonconforming outputs in one or more of the following ways:

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8.7.1.2.1 rework to meet specifications;

8.7.1.2.1.1 Conformity to the requirements shall be verified when nonconforming outputs are corrected.

8.7.1.2.2 segregation, containment, return or suspension of provision of products and services;

8.7.1.2.3 informing the customer;

8.7.1.2.4 obtaining authorization for acceptance under concession.

8.7.1.2.5 acceptance with or without repair, taking into account urgent production needs;

8.7.1.2.6 return to vendor for replacement or credit;

8.7.1.2.7 rejection or scrap.

8.7.1.3 Quality records of nonconformance and corrective/preventive actions are recorded and maintained. Repaired/reworked product is re-inspected IAW QSPs.

8.7.1.4 A Materiel Review Board (MRB), chaired by the Chief, Production Engineering Division, has the authority to determine and make recommendations for disposition of nonconforming product.

8.7.2 The organization shall retain documented information that:

8.7.2.1 describes the nonconformity;

8.7.2.2 describes the actions taken;

8.7.2.3 describes any concessions obtained;

8.7.2.4 identifies the authority deciding the action in respect of the nonconformity.

9.0 PERFORMANCE EVALUATION

9.1 Monitoring, measurement, analysis and evaluation

9.1.1 General

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9.1.1.1 LEAD shall determine what needs to be monitored and measured and when.

9.1.1.2 LEAD shall plan and implement a monitoring, measurement, analysis, and improvement process to ensure conformity and effectiveness of the QMS.

9.1.1.3 Procedures shall be developed for the planning and implementation of monitoring, measurement, analysis and improvement processes needed to demonstrate validity of results obtained, conformance to product requirements, conformity to the QMS, and the continuous improvement of the QMS (See QSP 6, Corrective/Preventive Action; QSP 7; QSP 13; QSP 14, Inspection and Testing; QSP 15, Statistical Process Control; QSP 17; and QSP 20).

9.1.1.4 Processes and products are evaluated for possible application of statistical techniques. Statistical techniques are implemented for verification, acceptability of process capability, continuous improvement, and product characteristics, when possible.

9.1.1.5 Where possible, statistical techniques such as inspection of key characteristics, process capability measurements, SPC and Design of Experiment (DOE) are used to analyze data obtained from monitoring and measurement with the results used to plan for measurement and monitoring activities so that desired production outcomes are satisfied. Statistical process and control charts are a few of the statistical techniques used to support design verification, process control, inspection, Failure Mode, Effect and Criticality Analysis (FMECA).

9.1.1.6 LEAD shall evaluate the performance and the effectiveness of the QMS and shall retain appropriate documented information as evidence of the results.

9.1.1.7 Monitoring and Measurement of Processes

9.1.1.7.1 LEAD maintains procedures for monitoring and measuring the QMS processes, to ensure processes deliver the planned results. The QM reviews and analyzes audit results to assess the effectiveness of the QMS.

9.1.1.7.2 Procedures include internal audits, surveillance inspections, individual employee certification, and receiving, in-process, and final inspections (See QSP 4; QSP 14; and QSP 15).

9.1.1.7.3 When planned results are not achieved, corrective actions are implemented and its effectiveness monitored.

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9.1.1.7.4 In the event of process nonconformity, appropriate action is taken to correct the nonconformity and determine if process nonconformity has resulted in product nonconformity. Any nonconforming products are identified and controlled.

9.1.1.7.5 Determine if process nonconformity is limited to a specific case or whether it could have affected other processes or products.

9.1.1.8 Monitoring and Measurement of Product

9.1.1.8.1 LEAD maintains and implements procedures for monitoring and measuring the product throughout all phases of production to verify product requirements are achieved.

9.1.1.8.2 In-process inspection and testing is performed at appropriate points to verify conformity of product to specification and quality requirements (See QSP 14).

9.1.1.8.3 Final inspection and testing is performed to verify product conformance to specified requirements. Prior to shipment, all specified inspections and tests are completed according to established procedures.

9.1.1.8.4 Quality records of inspections, *acceptance criteria, sequence of measurement* and tests are maintained as evidence of conformity with the acceptance criteria. These records identify whether the product passed or failed the specified inspections/tests. Quality records validate only products conforming to customer requirements are released.

9.1.1.8.5 *LEAD shall provide objective evidence that all maintenance operations have been completed as planned. Measurement requirements for product or service acceptance shall be documented and shall include:*

9.1.1.8.5.1 *criteria for acceptance and/or rejection;*

9.1.1.8.5.2 *where in the sequence measurement and testing operations are to be performed, including required customer and/or Authority inspection;*

9.1.1.8.5.3 *required records of the measurement results (at a minimum, indication of acceptance or rejection);*

9.1.1.8.5.4 *any specific measurement instruments required and any specific instructions associated with their use;*

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9.1.1.8.5.5 *identification of which inspection and testing operations are to be verified and/or witnessed.*

9.1.1.8.6 *Critical items including key characteristics, have been identified and monitored IAW established processes.*

9.1.1.8.7 *Surveillance plans are justified on the basis of recognized statistical principles and are appropriate for use (i.e., matching the sampling plan to the criticality of the product and to the process capability).*

9.1.1.8.8 *LEAD shall identify defects discovered during maintenance that are outside the scope of the maintenance contract and shall process them IAW customer and Authority requirements.*

9.1.1.8.9 *Where product is released for maintenance use pending completion of all required measurement and monitoring activities, it shall be identified and recorded to allow recall and replacement if it is subsequently found that the product does not meet requirements.*

9.1.1.8.10 *Test records shall show actual test results data when required by specification or acceptance test plan. Where required to demonstrate product qualification, LEAD shall ensure that records provide evidence that the product meets the defined requirements.*

9.1.1.8.11 *Release of product and delivery of service to the customer shall not proceed until the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer.*

9.1.1.8.12 *All documents required to accompany the product shall be present at delivery. Procedures shall be implemented for the preparation and completion of the Authority documentation (e.g., conformity determination, airworthiness approvals, release certificates, approval for return to service after maintenance, and export documentation).*

9.1.2 Customer Satisfaction

9.1.2.1 LEAD shall monitor customers' perceptions of the degree to which their needs and expectations have been fulfilled. LEAD shall determine the methods for obtaining, monitoring and reviewing this information.

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9.1.2.2 One of the performance benchmarks of the QMS is customer satisfaction and as such, LEAD monitors information related to customer satisfaction and the customers' perception as to whether their requirements have been met.

9.1.2.3 LEAD ensures external customers are identified and communicated throughout the organization. A formal channel of communication is established to determine customer satisfaction. Customer feedback is documented and available for review. Responses are timely and customer-oriented, with follow-up, if necessary.

9.1.2.4 QSPs are established and maintained to monitor customer satisfaction. Customer satisfaction is measured via customer surveys/other documented means (See QSP 8).

9.1.2.5 DPA is responsible for developing customer surveys, soliciting customer feedback, maintaining the customer service "Hotline", etc.

9.1.2.6 DPA shall implement plans for customer satisfaction improvement based on deficiencies identified by customer responses, and assess the effectiveness of the results.

9.1.3 Analysis and evaluation

LEAD shall analyze and evaluate appropriate data and information arising from monitoring and measurement. The results of analysis shall be used to evaluate:

9.1.3.1 conformity of products and services;

9.1.3.2 the degree of customer satisfaction;

9.1.3.3 the performance and effectiveness of the quality management system;

9.1.3.4 if planning has been implemented effectively;

9.1.3.5 the effectiveness of actions taken to address risks and opportunities;

9.1.3.6 the performance of external providers;

9.1.3.7 the need for improvements to the quality management system.

9.1.4 LEAD utilizes statistical techniques and methods to analyze data for customer satisfaction, conformance to product requirements, process and product performance, and to demonstrate the suitability and effectiveness of the QMS (See QSP 15).

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9.1.5 Analysis of data shall also provide information related to external providers, human factors events, and opportunities for corrective and preventive actions.

9.1.6 DPA is responsible for collecting and analyzing statistical data for all process owners.

9.2 Internal Audit

9.2.1 The QM is responsible for managing an internal quality audit program. Internal quality audits are performed at planned intervals to determine the effectiveness of and compliance to the QMS and the requirements of the international standards. An audit schedule for all clauses of the ISO 9001:2015, ISO 14001:2015, and OHSAS 18001:2007 standards is developed based on historical activity data and new product launches.

9.2.2 QSPs are established and maintained to ensure compliance and effectiveness of the QMS IAW documented procedures, customer contractual requirements, and any legal requirements (See QSP 4, Internal Audits).

9.2.3 Trained and competent auditor personnel independent of the area being audited will conduct internal quality audits. Audit reports are prepared and results of audits are submitted to the process owner for evaluation, and if necessary, root cause analysis and corrective/preventive action. Follow-up audits are performed to verify and record the implementation and effectiveness of actions taken. Records of quality audits and follow-ups are maintained.

9.2.4 The QM is responsible for briefing the Commander on the effectiveness of the internal quality audit program.

9.3 Management Review

9.3.1 General

The QM shall conduct a QMR with the Commander, Deputy to the Commander, special staff representatives, and all directors in attendance at planned intervals in order to determine the continuing suitability, adequacy, effectiveness, and alignment of the QMS (See QSP 20) with the strategic direction of LEAD. The QMR shall also assess the opportunities for improvement and the need for changes to the *Quality Policy and the Quality Objectives*.

9.3.2 Management Review Inputs

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The management review shall be planned and carried out taking into consideration:

9.3.2.1 the status of actions from previous management reviews;

9.3.2.2 changes in external and internal issues that are relevant to the quality management system;

9.3.2.3 information on the performance and effectiveness of the QMS, including trends in customer satisfaction and feedback from relevant interested parties, the extent to which quality objectives have been met, process performance and conformity of products and services, nonconformities and corrective actions, monitoring and measurement results, audit results, and the performance of external providers;

9.3.2.4 the adequacy of resources;

9.3.2.5 the effectiveness of actions taken to address risks and opportunities (see 6.1);

9.3.2.6 opportunities for improvement.

9.3.3 Management Review Output

9.3.3.1 The outputs of the management review shall include decisions and actions related to:

9.3.3.1.1 opportunities for improvement;

9.3.3.1.2 any need for changes to the QMS;

9.3.3.1.3 resource needs.

9.3.3.2 LEAD shall retain documented information as evidence of the results of management reviews.

9.3.3.3 The Commander determines any changes needed within the QMS, based on the results of the QMR. Provisions for adequate resources are made in order to improve customer satisfaction and the effectiveness of QMS.

10.3 Continual improvement

LEAD shall continually improve the suitability, adequacy and effectiveness of the QMS.

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10.3.1 LEAD continuously improves the effectiveness of the QMS through the use of the Quality Policy, Quality Objectives, audit results, data analysis, corrective/preventive action, and the QMR.

10.3.2 LEAD monitors the implementation of improvement activities and evaluates the effectiveness of the results.

10.3.3 LEAD uses LEAN tools and principles along with results from lessons learned, problem resolutions, and bench marking of best practices throughout the depot to improve workflow and processes (See QSP 17).

10.3.4 Corrective and Preventive Action

10.3.4.1 QSPs for corrective/preventive actions are established and maintained. Changes to QSPs resulting from corrective/preventive actions are recorded and maintained. Quality records for each corrective/preventive action are maintained, as defined by the customer (See QSP 6).

10.3.4.2 Corrective actions for non-conformities related to product, processes, procedures, documentation, or the QMS, are initiated through customer complaints, Hotline calls, reports of discrepancies, internal investigation of non-conformities and audits, etc.

10.3.4.3 Each request for corrective action is investigated for root cause and analyzed for appropriate corrective action. Process owners are responsible for analyzing non-conformities for root cause and for implementing corrective action. All steps taken in relation to corrective action shall be documented for review. Follow-up is performed to ensure corrective action is effective.

10.3.4.4 Requests for preventive action are initiated as a result of quality audits, as outlined in the QSPs. All steps taken in relation to corrective/preventive action are documented for review. Follow-up is performed to ensure corrective/preventive action is effective.

10.3.4.5 The QM provides status on corrective/preventive action reviewed at the depot QMR.

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INTRANET QUALITY SYSTEM CONTROLLED**APPENDIX A****A-1.0 LIST OF ACRONYMS**

3P	Production Process Preparation Events
ACC	Army Contracting Command
ACI	American Concrete Institute
ADA	Americans with Disability Act -1990
ADP	Automatic Data Processing
AIEP	Army Ideas for Excellence Program
ALCS	Automated Logistics Control System
AMC	Army Materiel Command
AMCOM	Aviation and Missile Command
AMC	ARMY Material Command
AMS	Asset Management System
ANSI	American National Standards Institute
API	American Petroleum Institute
APN	Army Part Number
AR	Army Regulation
AS	Aerospace Standard
ASFI	Army Single Face to Industry
ASME	American Society of Mechanical Engineers
ASNT	American Society of Nondestructive Testing
ASRS	Automated Storage & Retrieval System
AST	Aboveground Storage Tank
ATE	Automatic Test Equipment
BDO	Business Development Office
BOM	Bill of Materials
BPA	Blanket Purchase Agreements
C&RS	Calibration & Repair Support
CAB	Corrective Action Board
CAPA	Corrective and Preventive Action
CAS	Clark & Stender Inc.
CASL	Competition Advocate Shopping List
CAT	Corrective Action Team
CBU	Calibrate Before Use
CC	Condition Code
CCR	Central Contractor Registration
CES	Cost Estimating System
CEDRS	Capability Engineering Data Reporting System
CERCLA	Comprehensive Environmental Response, Compensation and Liability Act
CF	Configuration Management

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INTRANET QUALITY SYSTEM CONTROLLED**APPENDIX A - continued**

CFA	Cognizant Field Activity
CFR	Code of Federal Regulations
CNR	Calibration Not Required
COQ	Cost of Quality
COR	Contracting Officer's Representative
CPG	Common Point Ground
CRAF-L	Certified Round Assembly Facility - LEAD
CRDM	Certified Round Data Management
CSP	Combined Spares Pool
CSR	Customer Service Representative
CTX	Center of Technical Excellence
DA	Department of the Army
DA	Dispositioning Authority
DAD	Document and Data
DCC	Defect Characteristic Code
DCO	Document Control Officer
DCR	Document Change Request
DFAS	Defense Finance Accounting Service
DIO	Directorate of Industrial operations
DLA	Defense Logistics Agency
DMISA	Depot Maintenance Inter-service Support Agreement
DMSMS	Diminishing Manufacturing Sources and Material Shortages
DMWR	Depot Maintenance Work Requirement
DOC	Directorate of Contracting
DOD	Department of Defense
DOE	Design of Experiment
DOIM	Directorate of Information Management
DOPS	Directorate of Operations Planning and Support
DOT	Department of Transportation
DPA	Directorate of Product Assurance
DPW	Directorate of Public Works
DRM	Directorate of Resource Management
DRSK	Directorate of Risk Management
DS&T	Directorate of Supply & Transportation
ECP	Engineering Change Proposal
EDA	Electronic Data Access
EDCS	Enhanced Data Collection System
EDI	Electronic Data Interchange
EDIS	Engineering Data Information System
EIR	Equipment Improvement Record

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INTRANET QUALITY SYSTEM CONTROLLED**APPENDIX A - continued**

EMD	Environmental Management Division
EMS	Environmental Management System
EPA	Environmental protection Agency
EQCC	Environmental Quality Control Committee
ESD	Electrostatic Discharge
ESDS	Electrostatic Discharge Susceptible
ESDSI	Electrostatic Discharge Susceptible Item
ETM	Electronic Technical Manual
FAT	First Article Test
FEDLOG	Federal Logistics (Database)
FED-STD	Federal Standard
FEMS	Federal Equipment Management System
FIFO	First-In, First-Out
FIR	Final Inspection Record
FMEA	Failure Modes and Effect Analysis
FMECA	Failure Mode, Effect and Criticality Analysis
FMS	Foreign Military Sales
FO	Foreign Object
FOD	Foreign Object Damage
FSC	Federal Supply Classification
FY	Fiscal Year
GAA	Grease, Automotive, and Artillery
GFM	Government Furnished Material
GIDEP	Government Industry Data Exchange Program
GPE	Government Point of Entry
GSA	General Services Administration
HMAG	Hazardous Material Approval Group
HMIS	Hazardous Material Identification System
HAZMAT	Hazardous Material
HCP	Hazmat Control Point
HMMS	Hazardous Material Management System
IADs	Immediate Action Directives
IAQG	International Aerospace Quality Group
IAW	In Accordance With
IBD	Industrial Business Division
ICE	Interactive Customer Evaluation
ICRC	Internal Calibration Repair Center
IMRF	Instrument Master Record File
IRP	Initial Receiving point
ISA	Installation Supply Activity

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INTRANET QUALITY SYSTEM CONTROLLED**APPENDIX A - continued**

ISSA	Interservice Support Agreements
ISO	International Organization for Standardization
ISSO	Information System Security Officer
IT	Information Technology
IWTP	Industrial Wastewater Treatment Plant
JSA	Job Safety Analysis
LCMC	Life Cycle Management Command
LD	Logistics Division
LEAD	Letterkenny Army Depot
LEMC	Letterkenny Munition Center
LMP	Logistics Modernization Program
LMS	Logistics Management Specialist
LO	Lubrication Order
LOGSA/LIDB	Logistics Support Activity/Logistics Intelligence Data Base
LOI	Letter of Instructions
LPS	Lightning Protection System
LRU	Line Replacement Unit
LTPO	Lower Tier Project Office
MDA	Missile Defense Agency
MFR	Memorandum for Record
MIPR	Military Interdepartmental Purchase Request
MILSTRIP	Military Standard Requisitioning and Issue
MILSPEC	Military Specification
MOA	Memorandum of Agreement
MOS	Metal Oxide Semiconductor
MOU	Memorandum of Understanding
MPT	Maintenance Part Technician
MR	Management Representative
MRB	Materiel Review Board
MRO	Material Release Order
MRO	Maintenance Repair and Overhaul
MROR	Maintenance, Repair, Overhaul, and Recertification
MRP	Materials Requirements Planning
MSC	Major Subordinate Command
MSDS	Material Safety Data Sheet
MSFS	Maintenance Shop Floor System
MWO	Modification Work Order
NACE	National Association of Corrosion Engineers
NBDS	New Business Development System
NDT	Nondestructive Testing

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INTRANET QUALITY SYSTEM CONTROLLED**APPENDIX A - continued**

NEC	National Electrical Code
NFPA	National Fire Protection Association
NICP	National Inventory Control Point
NIST	National Institute of Standardization and Technology
NMWR	National Maintenance Work requirement
NOR	Notice of Revision
NPDES	Natural Pollutant Discharge Elimination System
NSN	National Stock Number
OCI	Office of Continuous Improvement
OEM	Original Equipment Manufacturer
OHSAS	Occupational Health and Safety Assessment Series
OH&SMS	Occupational Health and Safety Management System
OJT	On the Job Training
OSO	Organizational Supply officer
PADEP	Pennsylvania Department of Environmental Protection
PAO	Public Affairs Office
PAT	Process Action Team
PCN	Project Change Notice
PCN	Project Control Number
PD2	Procurement Desktop Defense
PDF	Portable Document Format
PED	Production Engineering Division
PEI	Petroleum Equipment Institute
P&IM	Policy and Instruction Memorandum
PIMS	PATRIOT Information Management System
PIR	PATRIOT Investigation Request
PM	Preventive Maintenance
PM	Program Manager
PMF	PATRIOT Missile Facility
PMSC	PATRIOT Missile Support Center
PN	Part Number
PO	Production Order
POC	Point of Contact
POL	Petroleum, Oils, and Lubricants
PPE	Personal Protective Equipment
PPQ	Process and Product Quality
PQDR	Product Quality Deficiency Report
PQS	PATRIOT Query System
PURs	Participant Utilization Reports
PURS	Participant Utilization Report System

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INTRANET QUALITY SYSTEM CONTROLLED**APPENDIX A - continued**

QA	Quality Assurance
QASAS	Quality Assurance Specialists Ammunition Surveillance
QC	Quality Control
QDP	Quality Data Package
QM	Quality Manager
QMR	Quality Management Review
QMS	Quality Management System
Q&R	Quality and Reliability
QSL	Quality Status List
QSM	Quality System Manual
QSP	Quality System Procedure
RAO	Responsible Action Officer
RCN	Report Control Number
RFI	Request for Information
RIA	Raytheon Internal Alerts
RIE	Rapid Improvement Event
RCO	Record Control Officer
RFD	Request for Deviation
RFQ	Request for Quote
RFW	Request for Waiver
ROD	Report of Discrepancy
RMS	Root Mean Square
R&R	Repair and Return
SAIC	Science Applications International Corporation
SAMD	Security Assistance Management Directorate
SAT	Simplified Acquisition Threshold
SBP	Strategic Business Plan
SDR	Supply Discrepancy Report
SDS	Safety Data Sheet
SF	Standard Form
SLES	Shelf-Life Extension System
SME	Subject Matter Expert
SMU	Statement of Mutual Understanding
SOP	Standing Operating Procedure
SOS	Source of Supply
SOW	Scope/Statement of Work
SPC	Statistical Process Control
SSPC	Structures Painting Council
STI	Steel Tank Institute

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INTRANET QUALITY SYSTEM CONTROLLED**APPENDIX A - continued**

STP	Sewage Treatment Plant
Sub-HCP	Subordinate HAZMAT Control Point
TAMMS	The Army Maintenance Management System
TB	Technical Bulletin
TDP	Technical Data Package
TDR	Transportation Discrepancy Report
TDS	Test Data Sheet
TDY	Temporary Duty
TED	Total Employee Development
TIR	Technical Investigation Request (HAWK)
TM	Technical Manual
TMDE	Test, Measurement, and Diagnostic Equipment
TMS	Training Management System
TO	Technical Order
TP	Technical Procedures
TPOC	Technical Point of Contact
TRMD	Theater Readiness Monitoring Directorate
TRMF	Theater Readiness Monitoring Facility
TSA	TMDE Support Activity
TSC	TMDE Support Center
TSM	TMDE Support Manager
UDR	Urgent Data Request
UFC	Unit Funded Cost
UIC	Unit Identification Code
UL	Underwriters Laboratories Incorporated
USATA	US Army Test, Measurement, and Diagnostic Equipment Activity
UST	Underground Storage Tank
VOC	Volatile Organic Compound
VOM	Volt-Ohm Meter
WBS	Work Breakdown Structure
WI	Work Instructions
WPC	Work Performance Code

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INTRANET QUALITY SYSTEM CONTROLLED**APPENDIX B****B-1.0 Quality System Procedures**

NUMBER	TITLE
QSP 1	Management Responsibility
QSP 2	Control of Documented Information
QSP 3	Control of Records
QSP 4	Internal Audits
QSP 5	Control of Nonconforming Product
QSP 6	Corrective/Preventive Action
QSP 7	Control of Monitoring and Measuring Equipment
QSP 8	Customer Satisfaction
QSP 9	Identification and Traceability (Tagging)
QSP 10	Shelf-Life
QSP 11	Workload Acceptance
QSP 12	Customer Property
QSP 13	Process Control
QSP 14	Inspection and Testing
QSP 15	Statistical Process Control
QSP 16	Servicing
QSP 17	Continuous Improvement
QSP 18	Infrastructure/Work Environment
QSP 19	Purchasing
QSP 20	Management Review
QSP 21	Control of Electrostatic Discharge
QSP 22	Foreign Object Damage (FOD) Prevention & Control
QSP 23	Government Industry Data Exchange program (GIDEP)
QSP 24	Risk and Opportunity Management

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