



# AEROSPACE STANDARD

AS13100™

Issued

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## AESQ Quality Management System Requirements for Aero Engine Design and Production Organizations

### RATIONALE

This standard has been created by the SAE G-22 Aerospace Engine Supplier Quality (AESQ) Technical Committee to harmonize and simplify supplier quality requirements that are in addition to the requirements of 9100 Quality Management Systems - Requirements for Aviation, Space, and Defense Organizations and 9145 Advanced Product Quality Planning and Production Part Approval Process.

Previously the Aerospace Engine Manufacturers based their supplier quality requirements on 9100 but had differing supplemental requirements and guidance albeit with largely the same intent. These supplemental requirements originate from the need to meet Regulatory, Customer, Industry, and Business requirements that are not explicitly covered by 9100 and 9145.

This standard sets out to create a common set of supplemental requirements with common reference materials to improve understanding, efficiency, and performance. While significantly simplifying the businesses of suppliers with multiple customers, the primary intent of this new standard is to improve overall product quality by focusing on the key systems and processes currently deterring consistent aerospace engine product quality.

These common supplemental requirements aim to raise the bar for anticipated performance in these key areas, and therefore detailed guidance is provided to ensure clarity of expectations.

### FOREWORD

To assure customer satisfaction, the aviation, space, and defense industry organizations have to produce and continually improve safe, reliable products that equal or exceed customer and regulatory authority requirements.

The globalization of the industry and the resulting diversity of regional/national requirements and expectations have complicated this objective. End-product organizations face the challenge of assuring the quality of and integration of product purchased from suppliers throughout the world and at all levels within the supply chain. Industry suppliers face the challenge of delivering product to multiple customers having varying quality expectations and requirements.

The SAE G-22 Aerospace Engine Supplier Quality (AESQ) Technical Committee was established under the SAE Aerospace Council to develop, specify, maintain, and promote quality standards relating to the aerospace engine supply chain. The principles defined within this standard may be applicable to other segments of the aviation, space, and defense industries.

The AESQ strategy is to promote defect prevention approaches across the supply chain including those associated with Advanced Product Quality Planning and Process Control to enable the supply chain to achieve Zero Defects.

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## INTRODUCTION

The Aerospace Engine Supplier Quality (AESQ) Group was formed in 2013 by Rolls-Royce, Pratt & Whitney, GE Aviation, and Safran Aircraft Engines with the objective of harmonizing and simplifying their Supplier Quality Management requirements.

Over the years each Engine manufacturer had developed their own set of supplier requirements to supplement those already defined in 9100 or ISO 9001. These supplemental requirements were intended to capture the requirements of their Regulators, Customers, and Industry as well as those of the Engine Manufacturer's business that were not covered in the scope of the 3rd party standards.

The AESQ recognized that as most of their supplemental requirements came from the same source it should be possible to harmonize a significant proportion of their supplier requirements into a single standard.

The Engine Manufacturers formed a Technical Committee (G-22) under the SAE Aerospace Council and were joined by major global suppliers Honeywell, GKN, MTU, PCC, IHI and Howmet to help develop these standards.

The AESQ created a Vision Statement to communicate its goals, see Figure 1.

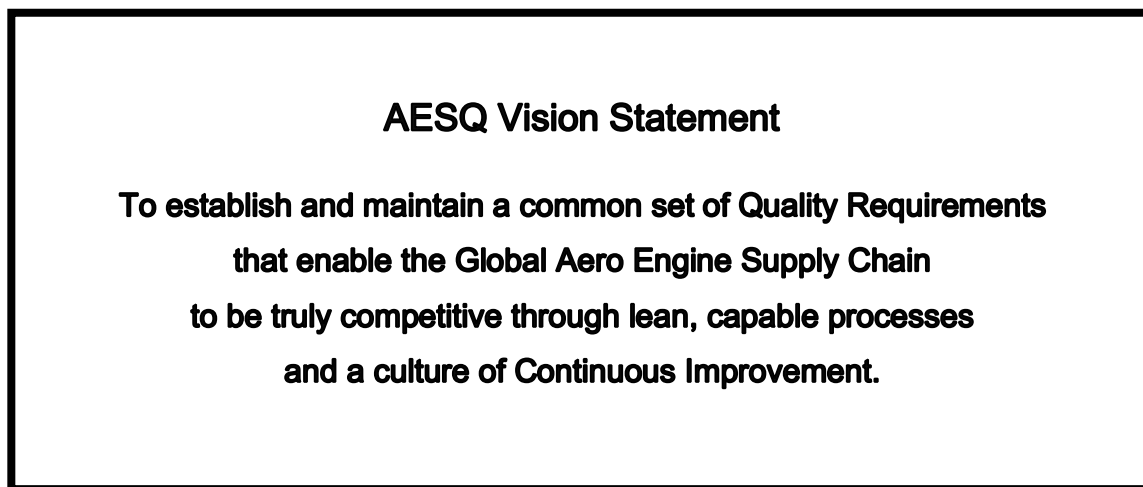


*Figure 1 - AESQ vision statement*

The AESQ defined objectives are to:

1. Simplify and Standardize supplier requirements.
2. Build on existing industry standards where possible.
3. Create a common language for Quality throughout the Supply Chain.
4. Publish Standards that are simple, prescriptive, and auditable.
5. Adopt easily within existing process/systems.
6. Deliver results rapidly, through focused activities.

Since 2013, AESQ have developed and published a number of quality management standards to begin this journey.

In 2018, the AESQ decided to further harmonize and replace the current AS130xx series of standards (excluding AS13001) by creating a single principal standard, AS13100, that aligns to 9100 and 9145 which includes all the requirements of the AS13XXX standards, with the exception of AS13001 - Delegated Product Release Verification Requirements. The standard, AS13100, would also include other quality subjects not previously addressed by the AESQ.

The current AS130xx which will be superseded are:

AS13000 - Problem Solving Requirements for Suppliers - Superseded by AS13100 & RM13000.

AS13002 - Requirements for Developing and Qualifying Alternate Inspection Frequency Plans - Superseded by AS13100 & RM13002.

AS13003 - Measurement Systems Analysis Requirements for the Aero Engine Supply Chain - Superseded by AS13100 & RM13003.

AS13004 - Process Failure Mode and Effects Analysis (Process FMEA) and Control Plans - Superseded by AS13100 & RM13004.

AS13006 - Process Control Methods - Superseded by AS13100 & RM13006.

For an overview of the linkage between AS13100 and other industry standards, Appendix A - Figure 7 shows the relationship between the current Quality Management System standards and AS13100. It can be noted that 9100 follows the structure of ISO 9001 and adds its own industry specific supplemental requirements.

AS13100 now does the same by building on the elements of ISO 9001, 9100, and 9145 to add the aero engine manufacturers specific requirements that are not covered in the other standards.

To help demonstrate the alignment with these standards the AS13100 supplemental requirements follow the same numbering sequence (clause Numbers, see Figure 2) as 9100 in AS13100 - Chapter A and 9145 in AS13100 - Chapter B.

| Management Standards |                                          | Clause Numbers |   |   |   |   |   |   |   |   |    |
|----------------------|------------------------------------------|----------------|---|---|---|---|---|---|---|---|----|
| ISO9001              | Any Industry Quality Management Standard | 1              | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |

|      |                                                                  |                                                                                                        |   |   |   |   |   |   |   |   |    |
|------|------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------|---|---|---|---|---|---|---|---|----|
| 9100 | Aviation, Space and Defense Industry Quality Management Standard | 1                                                                                                      | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
|      |                                                                  | Defines supplementary requirements to ISO9001. ISO 9001 requirements are included within 9100 in full. |   |   |   |   |   |   |   |   |    |

| 9145 | APQP / PPAP Standard for Aviation, Space and Defense Industry |  |  |  |  |  |  |  |  |  |  | Clause Numbers |     |   |   |   |   |   |
|------|---------------------------------------------------------------|--|--|--|--|--|--|--|--|--|--|----------------|-----|---|---|---|---|---|
|      |                                                               |  |  |  |  |  |  |  |  |  |  | 0.1            | 0.2 | 1 | 2 | 3 | 4 | 5 |

|         |                                                |                                                           |   |   |   |   |   |   |   |   |    |                                            |    |    |    |    |    |    |
|---------|------------------------------------------------|-----------------------------------------------------------|---|---|---|---|---|---|---|---|----|--------------------------------------------|----|----|----|----|----|----|
| AS13100 | Aero Engine Quality Management System Standard | 1                                                         | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11                                         | 12 | 13 | 14 | 15 | 16 | 17 |
|         |                                                | Defines supplementary requirements to 9100 and/or ISO9001 |   |   |   |   |   |   |   |   |    | Defines supplementary requirements to 9145 |    |    |    |    |    |    |

**Figure 2 - AS13100 standard relationship to other quality management system standards**

AS13100 is supported by a series of Reference Manuals that provide additional detail on certain subjects to describe the intent of the standard and to provide guidance on deployment. For an index of these Reference Manuals, see 2.2 - AESQ Publications.

Further information on the work of the AESQ can be found on their website <https://aesq.sae-itc.com>.

## 1. SCOPE

This standard establishes supplemental requirements for 9100 and 9145 and applies to any organization receiving it as part of a Purchase Order or other contractual document from a customer.

AS13100 also provides details of the Reference Materials (RM13xxx) developed by the SAE G-22 AESQ committee and listed in Section 2 - Applicable Documents, that can also be used by organizations in conjunction with this standard.

## 2. APPLICABLE DOCUMENTS

The following publications form a part of this document to the extent specified herein. The latest issue of SAE publications shall apply. The applicable issue of other publications shall be the issue in effect on the date of the purchase order. In the event of conflict between the text of this document and references cited herein, the text of this document takes precedence. Nothing in this document, however, supersedes applicable laws and regulations unless a specific exemption has been obtained.

### 2.1 SAE Publications

Available from SAE International, 400 Commonwealth Drive, Warrendale, PA 15096-0001, Tel: 877-606-7323 (inside USA and Canada) or +1 724-776-4970 (outside USA), [www.sae.org](http://www.sae.org).

|         |                                                                                                                                      |
|---------|--------------------------------------------------------------------------------------------------------------------------------------|
| AS13001 | Delegated Product Release Verification Training Requirements                                                                         |
| AS5553  | Counterfeit Electrical, Electronic, and Electromechanical (EEE) Parts: Avoidance, Detection, Mitigation, and Disposition             |
| AS6174  | Counterfeit Materiel; Assuring Acquisition of Authentic and Conforming Materiel                                                      |
| 9100*   | Quality Management Systems - Requirements for Aviation, Space, and Defense Organizations                                             |
| 9102*   | Aerospace First Article Inspection Requirement                                                                                       |
| 9103    | Aerospace Series - Quality Management Systems - Variation Management of Key Characteristics                                          |
| 9115*   | Quality Management Systems - Requirements for Aviation, Space, and Defense Organizations - Deliverable Software (Supplement to 9100) |
| 9116*   | Notice of Changes (NOC) Requirements                                                                                                 |
| 9117*   | Delegated Product Release Verification                                                                                               |
| 9120*   | Quality Management Systems - Requirements for Aviation, Space and Defense Distributors                                               |
| 9145*   | Aerospace Series - Requirements for Advanced Product Quality Planning and Production Part Approval Process                           |
| 9146*   | Foreign Object Damage (FOD) Prevention Program - Requirements for Aviation, Space, and Defense Organizations                         |
| 9162*   | Aerospace Operator Self-Verification Programs                                                                                        |
| SCMH    | IAQG Supply Chain Management Handbook                                                                                                |

NOTE: \*Internationally harmonized standards developed under the authority of the IAQG and listed here, as SAE International “AS” publications. Equivalent versions may be published by other standards bodies (e.g., European Committee for Standardization (CEN), Japanese Standards Association/Society of Japanese Aerospace companies (JSA/SJAC).

## 2.2 AESQ Publications

The AESQ Reference Manuals have been created to support the requirements of AS13100 by providing examples of acceptable means of compliance. These documents provide methodologies, templates, and case studies of the application of key processes required by the standard.

The intent of these Reference Manuals is to standardize the processes and language for quality across the Aero Engine supply chain.

In each case alternative approaches may be used if they meet the same intent and are agreed with the customer.

Copies of RM13xxx documents are available online at <https://aesq.sae-itc.com/supplemental-material>.

|         |                                                                                                                                 |
|---------|---------------------------------------------------------------------------------------------------------------------------------|
| RM13000 | Problem Solving Methods including 8D                                                                                            |
| RM13002 | Alternate Inspection Frequency Plans                                                                                            |
| RM13003 | Measurement Systems Analysis (MSA)                                                                                              |
| RM13004 | Defect Prevention Quality Tools to support Advanced Product Quality Planning (APQP) and Production Part Approval Process (PPAP) |
| RM13005 | Quality Audit Methods                                                                                                           |
| RM13006 | Process Control Methods                                                                                                         |
| RM13007 | Sub-tier Management                                                                                                             |
| RM13008 | Design Work                                                                                                                     |
| RM13009 | AS13100 Compliance Matrix                                                                                                       |
| RM13010 | Human Factors                                                                                                                   |
| RM13011 | Managing Rework and Production Repair                                                                                           |
| RM13102 | First Article Inspection Requirements (FAIR)                                                                                    |
| RM13145 | Advanced Product Quality Planning (APQP) and Production Part Approval Process (PPAP)                                            |

## 2.3 PRI - Nadcap Audit Criteria Publications

The following Audit Criteria (AC) refer to Nadcap Special Process Checklists. Nadcap Certification is required by some customers. Copies of AC7xxx - Audit Criteria Publications are available online at <https://p-r-i.org/nadcap/accreditation/>.

|        |                                            |
|--------|--------------------------------------------|
| AC7130 | Measurement and Inspection                 |
| AC7004 | Aerospace Quality System                   |
| AC7008 | Subscriber Accreditation Option b HQ Audit |
| AC7108 | Chemical Processing                        |
| AC7109 | Coatings                                   |

|        |                                             |
|--------|---------------------------------------------|
| AC7118 | Composites                                  |
| AC7126 | Conventional machining as a Special Process |
| AC7115 | Elastomer Seals                             |
| AC7119 | Electronics                                 |
| AC7120 | Electronics                                 |
| AC7121 | Electronics                                 |
| AC7112 | Fluid Distribution Systems                  |
| AC7123 | Fluid Distribution Systems                  |
| AC7102 | Heat Treating                               |
| AC7101 | Materials Testing Laboratories              |
| AC7006 | Materials Testing Laboratories              |
| AC7114 | Nondestructive Testing                      |
| AC7116 | Nonconventional machining                   |
| AC7117 | Surface Enhancement                         |
| AC7124 | Nonmetallic Materials Manufacturing         |
| AC7122 | Nonmetallic Materials Testing               |
| AC7200 | Sealants                                    |
| AC7202 | Sealants                                    |
| AC7129 | Sealants                                    |
| AC7110 | Welding                                     |
| AC7135 | Aero Structure Assembly                     |
| AC7140 | Metallic materials                          |

## 2.4 Other Publications

Copies of ISO documents are available online at <https://webstore.ansi.org/>. Copies of APQP documents are available at [www.aiaq.org](http://www.aiaq.org). Copies of AWS documents are available from <https://www.aws.org/standards>. Copies of European Union Aviation Safety Agency (EASA) CS documents are available from <https://www.easa.europa.eu/>. Copies of VDA and EN standards are available from <https://www.en-standard.eu/>. Copies of NAS standards are available from <https://www.aia-aerospace.org/standards>. Copies of SNT document is available from <https://www.asnt.org/>.

|          |                                                                                                                   |
|----------|-------------------------------------------------------------------------------------------------------------------|
| APQP     | Advanced Product Quality Planning and Control Plan; APQP Second Edition; Automotive Industry Action Group (AIAG). |
| ISO 9000 | Quality management systems - Fundamentals and vocabulary.                                                         |
| ISO 9001 | Quality management systems - Requirements.                                                                        |

|               |                                                                                                                                   |
|---------------|-----------------------------------------------------------------------------------------------------------------------------------|
| ISO 9712      | Non-destructive testing - Qualification and certification of NDT personnel.                                                       |
| ISO 11745     | Brazing for aerospace applications - Qualification test for brazers and brazing operators - Brazing of metallic components.       |
| ISO 19828     | Welding for aerospace applications - Visual inspection of welds.                                                                  |
| ISO 24394     | Welding for aerospace applications - Qualification test for welders and welding operators - Fusion welding of metallic components |
| ISO 31000     | Risk Management - Guidelines.                                                                                                     |
| ISO/IEC 17025 | General Requirements for the Competence of Testing and Calibration Laboratories.                                                  |
| AWS D17.1     | Specification for Fusion Welding of Aerospace Applications.                                                                       |
| CS-E515       | EASA Certification Specification - Engine Critical Parts.                                                                         |
| EN4179        | Aerospace series. Qualification and approval of personnel for non-destructive testing.                                            |
| NAS410        | Certification and Qualification of Nondestructive Test Personnel.                                                                 |
| SNT-TC-1A     | Recommended Practice - Personnel Qualification and Certification in Nondestructive Testing.                                       |
| VDA6.3        | Quality Management - Automotive Industry - Process Audit.                                                                         |

### 3. TERMS AND DEFINITIONS

In this Aerospace Standard, the following verbal forms are used:

- “Shall” indicates a requirement.
- “Should” indicates a recommendation.
- “May” indicates a permission.
- “Can” indicates a possibility, or a capability.

Information marked as “NOTE:” is for guidance in understanding or clarifying the associated requirement.

A list of acronyms used has been provided (see Appendix C).

For the purposes of this standard, terms and definitions stated in ISO 9000:2015 and the following apply:

#### BILL OF MATERIAL (BOM)

List of components and materials contained in the Design Record(s) of a product.

#### CALIBRATION SERVICE ORGANIZATION

An Organization qualified to perform calibration services on Measuring and Test Equipment (monitoring and measuring equipment) used in the production of products.

#### CHARACTERISTIC CLASSIFICATION

A classification given to characteristics to differentiate between an attribute or feature of different importance to the design [e.g., Key Characteristics (KC), Critical, Major, Minor].

#### CONTAINMENT

Action to control and mitigate the impact of a nonconformity and protect the customer's operation (stop the problem from getting worse); includes correction, immediate corrective action, immediate communication, and verification that the nonconforming situation does not further degrade.

#### CONTROL PLAN

A documented description linking manufacturing process steps to key inspection and control activities. The intent of a Control Plan is to control the design characteristics and the process variables to ensure product quality.

#### COMMERCIAL-OFF-THE-SHELF (COTS) ITEMS

Commercially available applications, defined by industry recognized specifications and standards, sold through public catalog listings.

#### COUNTERFEIT PART

An unauthorized copy, imitation, substitute, or modified part (e.g., material, part, component), which is knowingly misrepresented as a specified genuine part of an original or authorized manufacturer.

NOTE: Examples of a counterfeit part can include, but are not limited to, the false identification of marking or labeling, grade, serial number, date code, documentation, or performance characteristics.

## CRITICAL ITEM (CI)

Those items (e.g., functions, parts, software, characteristics, processes) having significant effect on the product realization and use of the product; including safety, performance, form, fit, function, producibility, service life, etc.; that require specific actions to ensure they are adequately managed. Examples include safety CIs, fracture CIs, mission CIs, Key Characteristics (KC), and maintenance tasks critical for safety.

## CRITICAL FEATURE

Those characteristics of an item which, if nonconforming, can result in hazardous or unsafe conditions for personnel using, maintaining, or depending on the product; or which can prevent or seriously affect the satisfactory operation or functioning of the product. Specific Customer Feature Classifications can exist.

## CRITICAL SAFETY ITEM(S)

A part, an assembly, installation equipment, launch equipment, recovery equipment, or support equipment for an aircraft or aviation weapon system, that contains a characteristic, which failure, malfunction, or absence of could cause a catastrophic or critical failure resulting in the loss of, or serious damage to, the aircraft, or weapon system, an unacceptable risk of personal injury or loss of life, or an un-commanded engine shutdown that jeopardizes safety.

NOTE 1: Catastrophic - A failure that could result in death, permanent total disability, and/or financial loss exceeding a defined contractual limit.

NOTE 2: Critical - A failure that could result in permanent partial disability and/or injuries or occupational illness resulting in hospitalization of at least three personnel.

NOTE 3: Life Limited Part - Per 14CFR 33.70 engine, Life Limited Parts (LLP) are rotor and major static structural parts whose primary failure is likely to result in a hazardous engine effect. Typically, engine LLP include, but are not limited to, disks, spacers, hubs, shafts, high pressure casings, and nonredundant mount components. LLP are equivalent to Engine Critical Parts under EASA certification per CS-E 510 and 515.

NOTE 4: Sensitive Part - Sensitive Parts (SP) are part's whose failure may, but is not likely to, result in a hazardous engine effect. The types of SP identified are a function of the specific engine architecture and therefore will vary from engine to engine.

## CUSTOMER

Organization, legal entity, or person that receives a product or service (e.g., consumer, client, end-user, retailer, beneficiary, purchaser).

## DELIVERABLE SOFTWARE

Embedded or loadable airborne, spaceborne, or ground support software or firmware components which are part of an aircraft type design, weapon system, missile, or spacecraft.

## DESIGN AUTHORITY

An organization with formal authority for the design, validation, and service support of a product.

NOTE: In civil aviation, this is the organization responsible for the design of articles or for changes thereto that is the holder of a design approval granted by a regulatory authority [i.e., Type Certificate (TC), Supplemental Type Certificate (STC), Parts Manufacturer Approval (PMA), Technical Standard Order (TSO)/Joint TSO/European TSO, European Part Approval (EPA) or equivalent].

## DESIGN CHANGE CLASS I AND CLASS II

### Class I Design Change

A Class I Design Change shall be classified and documented when any significant design factor needs to be changed outside of specified limits or specified tolerances, including, but not limited to, the following elements, e.g., safety, performance, including thermodynamic and mechanical performance (i.e., durability), reliability, maintainability, or survivability, weight, balance, moment of inertia, interface characteristics.

Any change which falls under the major classification of Part 21 - Airworthiness Certification, shall be documented as a Class I change.

### Class II Design Change

A Class II Design Change shall be classified and documented when the change introduced does not fall within the definition of a Class I design change.

## DESIGN CHARACTERISTIC/CHARACTERISTIC

Those dimensional, visual, functional, mechanical, and material features or properties, which describe and constitute the design of the article, as specified by drawing or Digital Product Definition (DPD) requirements. These characteristics can be measured, inspected, tested, or verified to determine conformance to the design requirements. Dimensional features include in-process locating features (e.g., target-machined, or forged/cast dimensions on forgings and castings, weld/braze joint preparation necessary for acceptance of finished joint). Material features or properties can include processing variables and sequences, which are specified by the drawing or DPD (e.g., heat treat temperature, fluorescent penetrant class, ultrasonic scans, sequence of welding and heat treat). These provide assurance of intended characteristics that could not be otherwise defined.

## DESIGN RECORD(S)

The records of the engineering definition/specification, which fully define the product (system, part, component, or assembly), including physical or electronic/digital drawings, electronic/digital models, software, or other associated information. This includes records of authorized engineering changes not yet incorporated into the released engineering definition/specification.

## DESIGN AND MANUFACTURE

An Organization providing products defined by a design/drawing proprietary to that Organization and linked to a part number through the use of a Customer-referenced drawing and/or other purchase order requirements (e.g., Source Control, Source Design, Engineered Item).

## DESIGN ONLY

An Organization providing design elements (i.e., results of design work activities) into a Design Technical Data Package (DTDP), including, any service, or development supplier who delivers design data, or other design decisions (e.g., engineering disposition of nonconformance) to be used by a Design Organization.

## DESIGN ORGANIZATION

An organization responsible for the design of articles or for changes thereto that is the holder of a Design Approval granted by a regulatory authority, i.e., Type Certificate (TC), Supplemental Type Certificate (STC), Technical Standard Order (TSO), Joint TSO (JTTSO), European TSO (ETSO), Parts Manufacturer Approval (PMA) authorization, or equivalent.

## DESIGN TECHNICAL DATA PACKAGE (DTDP)

The design outputs created during the product design lifecycle to support initial and continued airworthiness. The scope of the DTDP for the organization is determined by the Customer. The format, method and frequency of these deliverable outputs is related to the maturity of the product.

## DISTRIBUTOR

An Organization carrying out the purchase, storage, splitting or sale of products without affecting product conformity. Distributors are limited to Raw Materials, Industry Standard Parts, and Commercial-Off-The-Shelf (COTS) items.

## ELECTRONIC - FIRST ARTICLE INSPECTION REPORT (e-FAIR)

An electronic application, typically customer owned and/or controlled, that contains First Article Inspection Report (FAIR) documentation.

## ELECTRONIC SIGNATURE

Symbol or other data in digital form that is controlled and traceable to the formal statement or acknowledgment by a specific individual (e.g., acknowledgment of completion of a task, receipt of a document).

## FAILURE MODE AND EFFECTS ANALYSIS (FMEA)

A structured method for analyzing risk by ranking and documenting potential failure mode in a system, design, or process. The analysis includes:

- Identification of potential failures and their effects.
- Ranking of factors (e.g., severity, frequency of occurrence, detectability of the potential failures); and
- Identification and results of actions taken to reduce or eliminate risk.

The FMEA assists in the identification of CIs as well as key design and process characteristics, helps prioritize action plans for mitigating risk, and serves as a repository for lessons learned. Examples include, system FMEA, interface FMEA, design FMEA, and process FMEA.

## FIRST ARTICLE INSPECTION (FAI)

A planned, complete, independent, and documented inspection and verification process to ensure that prescribed production processes have produced an item conforming to engineering drawings, DPD, planning, purchase order, engineering specifications, and/or other applicable documented information (Design Records).

## FIRST ARTICLE INSPECTION REPORT (FAIR)

The forms and package of documentation for a part number, sub-assembly, or assembly, including associated FAI results, as defined by this standard.

## HUMAN FACTORS REPORTING

Refers to the reporting, collection and evaluation of human factor related events, hazards, or improvement opportunities. The purpose of this reporting is to ensure that the organization learns from these and reduces the error opportunity.

These reports may be part of the organizations existing incident reporting process or a separate process specifically for Human Factor related issues. Reports may be raised as a result of an event (nonconformance, customer escape, rework, etc.) or by a staff member, including those raised by the confidential reporting line.

## INDUSTRY STANDARD PART MANUFACTURER

A manufacturer of parts for which the design, manufacturing, inspection data, and marking requirements necessary to demonstrate conformity of the part are in the public domain and published or established as part of officially recognized standards [e.g., AN (Air Force-Navy Aeronautical Standard), AS (Aerospace Standard), MS (Military Standard), NAS (National Aerospace Standard)].

## INDUSTRY STANDARD RAW MATERIAL MANUFACTURER

A manufacturer of raw material that conforms to an established industry or national authority published specification [e.g., Aerospace Material Specification (AMS)].

## INTERIM CONTAINMENT ACTION (ICA)

Immediate containment actions taken in order to eliminate or significantly reduce the effect of the Failure Mode on the customer(s) until permanent corrective actions are in place and verified.

## KEY CHARACTERISTIC (KC)

An attribute or feature whose variation has a significant effect on product fit, form, function, performance, service life, or producibility, that requires specific actions for the purpose of controlling variation.

This definition is further explained as follows:

- Product or system KCs are those selected geometrical, material properties, functional, and/or cosmetic features, which are measurable, and whose variation control is necessary for fulfilling customer requirements and enhancing customer satisfaction.
- Process KCs are those selected measurable characteristics of a process whose control is essential to manage variation of product or system KCs.
- Substitute KCs can be identified when a customer defined KC is not readily measurable, within the production/ maintenance setting, and other characteristics may need to be controlled to ensure conformance.

NOTE: Design output can include identification of CIs that require specific actions to ensure they are adequately managed. Some CIs may be further classified as KCs because their variation needs to be controlled.

## LABORATORY SERVICE ORGANIZATION

An Organization qualified to perform testing services (e.g., chemical, metallurgical, electrical).

## MAJOR FEATURE

Those characteristics of an item, other than critical, which if nonconforming, can result in operational or functional failure of the item, or which materially reduce the usability, physical or functional interchangeability or durability of the product for its intended purpose. Specific feature specifications shall be defined by the customer.

## MAKE TO PRINT

An Organization responsible for the manufacture of products as defined by the Customer.

NOTE: Manufacture of castings and forgings are considered make to print parts.

## MEASUREMENT SYSTEMS ANALYSIS (MSA)

A study of the effects of selected elements of a measurement process (i.e., people, machines, tools, methods, materials, environment) on accuracy, precision, and uncertainty of measurement.

## MINOR FEATURE

Those characteristics of an item which, if nonconforming, do not materially reduce the usability, physical or functional interchangeability or durability of the product, or are a departure from established standards having no significant bearing on the effective use or operation of the product. Specific feature specifications shall be defined by the customer.

## NONDELIVERABLE SOFTWARE

Nondeliverable Software that directly relates to design, manufacture, inspection, test, or calibration of a deliverable product, and directly affects the configuration, conformity, or quality of a deliverable product.

## ORGANIZATION

Group of people and facilities with an arrangement of responsibilities, authorities, and relationships.

## PROCESS CAPABILITY

The ability of a process or product to consistently meet a specification or customer requirement (often expressed as a capability index, e.g., Cpk or Ppk).

## PROCESS CAPABILITY STUDY

A study that compares the output of an in-control process to the specification limits, expressed in terms of process **potential** capability index (e.g., Cpk) or as a process performance index [e.g., Ppk, Parts Per Million (PPM)].

## PROCESS STABILITY

A condition or state of behavior of a process where, through the use of past experience, near-term future behavior can be predicted reliably within limits. A condition where there is no indication of a special cause of variation, but where only random common cause variation is present.

## PRODUCT DEFINITION

Engineering requirements as documented within the Drawing, Key Characteristics, Drawing Notes, Engineering Specifications on the drawing, or referenced engineering specifications, including Digital Product Definition (DPD), and related documents (like Performance Table), as applicable.

## PRODUCT DEVELOPMENT PROCESS (PDP)

A generically applied term referring to an organization's process(es) for product realization. The process begins with conceptual product needs and expands throughout the life of the product. Common milestones include kick-off, end of concept [i.e., Preliminary Design Review (PDR)], design release [i.e., Critical Design Review (CDR)], initial production approval, and production launch.

## PRODUCT QUALITY ESCAPE

Any product released by an internal/external supplier or sub-tier supplier, that is subsequently determined to have one or more nonconformities to contract and/or product specification requirements, that have not been positively dispositioned prior to delivery.

## PRODUCT SAFETY

The state in which a product is able to perform to its designed or intended purpose without causing unacceptable risk of harm to persons or damage to property.

## PRODUCTION ACTIVITIES

The method of transforming the product, i.e., changing the geometry, product constituents, material properties, e.g., machining, welding, bonding, heat treatment, surface treatment, assembly.

## PRODUCTION INSPECTION EQUIPMENT

Equipment that is stored, operated, or controlled by production staff and is part of the planned production sequence and approved as capable.

## PRODUCTION ORGANIZATION

An organization, approved by an applicable regulatory authority, which is responsible for the manufacture of aeronautical articles.

## PRODUCTION REPAIR

Production Repair is an action on a nonconforming product in new part production to make it acceptable for the intended use. In conjunction with a production repair a concession is required.

## PRODUCTION SHOP ASSIST ONLY

An Organization receiving a purchase order from a customer to perform specific manufacturing processes as defined by the customer which typically replace an individual manufacturing process (e.g., turning operation, cutting risers, rough milling) in the customer's overall manufacturing process.

## PRODUCTION STAFF

Staff that carry out production activities including those authorized to carry out product verification (commonly referred to as operator certification/self-certification personnel).

## QUALITY PLANNING TOOLS

Refers to the Defect Prevention Quality tools that are integrated into Advanced Product Quality Planning and includes Design FMEA, Design Verification, Process FMEA, Pre-launch Control Plans, Production Control Plans, MSA, Initial Process Capability Studies.

## RAW MATERIAL

Basic material from which product is manufactured, i.e., the material called out at the lowest level of the design authority's bill of material (BOM) (e.g., bar, billet, sheet, tube, plate, powder).

## RAW MATERIAL ORGANIZATION

Organizations manufacturing Raw Materials to non-Industry Standard raw material specification.

## REACTION PLAN

A plan that specifies actions necessary to avoid producing nonconforming product, operating out of control and details containment action plans to be invoked when nonconforming product is detected.

## REDUCED INSPECTION

One of several levels of inspection connected by switching rules, which involves a lower fraction inspected than one or more of the others.

NOTE: In such a system the quality parameter is usually the Average Outgoing Quality Limit (AOQL) and that AOQL is maintained, despite the lower fraction inspected, by the fact that the process generally only gets to that level when the quality is as good as or better than the AOQL for some period of time.

## REPAIR

Repair is an action on a nonconforming product to make it acceptable for the intended use.

## REQUIREMENT

A requirement is a need, expectation, or obligation. It can be stated or implied by a supplier, its customers, or other interested parties. A specified requirement is one that has been stated - in a document, for example - whereas an implied requirement is a need, expectation, or obligation that is common practice or customary. There are many types of requirements. Some of these include quality requirements, customer requirements, management requirements, product requirements, statutory and regulatory, and legal requirements.

## REWORK

Rework is an action on a nonconforming product to make it conform to the requirements.

## SAMPLE INSPECTION

A type of alternate frequency inspection plan. The inspection of selected characteristics on sampled parts from which the conformity of the same characteristics on other parts is inferred.

## SIGNIFICANT CHANGE

Significant changes include, but are not limited to, changes in quality leadership, changes in scope, name, address, or approval status of QMS registrations, applicable Production Organization holder approvals, and special process accreditations.

## SPECIAL PROCESS(ES)

Any process for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement and, as a consequence, deficiencies become apparent only after the product is in use or the service has been delivered.

NOTE: Those processes often modify or change the inherent physical, chemical, electrical, or metallurgical properties of an item, or are nonconventional methods which remove or deposit material on the item during or after fabrication which cannot be fully evaluated by nondestructive means, or are those used to maintain process control, e.g., nondestructive testing.

## SPECIAL PROCESS ORGANIZATION

An Organization that only provides special processes on products (i.e., not a part manufacturing supplier).

## STANDARD PART

Parts for which the design, manufacturing, inspection data, and marking requirements necessary to demonstrate conformity to the part are in the public domain and published/established as part of the officially recognized standards.

## SUPPLIER

The entity or party that supplies product or services to a customer in accordance with contract requirements.

NOTE 1: Products and services can include: designs, production materials, production/service parts, assemblies, special processes (e.g., heat treatment, welding), or services to a customer in accordance with a contractual agreement.

NOTE 2: The term supplier is synonymous with the term external provider, contractor, organization, seller, or vendor.

## VALIDATION

Confirm through the provision of objective evidence, that the requirements (or specified intended use) have been fulfilled in the intended usage environment.

## VERIFICATION

Confirmation by examination and provision of objective evidence that the specified requirements have been fulfilled.

Relevant types of verification include:

- Design Verification - Confirmation through the provision of objective evidence, that the specified product requirements have been fulfilled. Testing and/or analysis to ensure that all design outputs satisfy requirements can include activities such as: design review, performing alternate calculations, understanding tests and demonstrations, and review of design stage documents before release (reference AIAG Advanced Product Quality Planning and Control Plan). This can involve pre-production products.
- Product Verification - The evaluation of a product's compliance to regulations, requirements, specifications, or physical conditions as designed. This is typically accomplished by testing and/or inspecting a product against its design requirements, i.e., FAI.

**AS13100 - Chapter A**  
**9100 Quality Management Systems - Requirements for Aviation, Space and Defense Organizations - AESQ**  
**Supplemental Requirements**

#### 4. CONTEXT OF ORGANIZATION

##### 4.1 Understanding the Organization and Its Context

Reference 9100D:09/2016 requirements.

##### 4.2 Understanding the Needs and Expectations of Interested Parties

Reference 9100D:09/2016 requirements.

##### 4.2.1 Understanding the Needs and Expectations of Interested Parties - Supplemental Requirements

The organization shall ensure on-site right of entry to its customers and their respective governmental and regulatory agencies, third parties mandated by the customer and contracting parties accompanying the customer's representatives including access to documented information and the ability to conduct audits, review of quality investigations, and to verify product and processes.

Right of entry includes access to the applicable areas of organization facilities as well as related supplier and business partner facilities.

Where access is restricted due to export control technical requirements or organization intellectual property concerns, the organization shall facilitate to allow the customer or regulatory agency to fulfil their mandate.

Where required the organization shall provide language translation services to support such reviews.

##### 4.3 Determining the Scope of the Quality Management System

Reference 9100D:09/2016 requirements.

##### 4.3.1 Determining the Scope of the Quality Management System - Supplemental Requirements

Table 1 contains the minimum requirements per supplier type and shall be reviewed in conjunction with additional Customer requirements. It shows the applicability of the AS13100 Standard clauses to the Organization's Scope of Approval.

Table 1 takes into consideration the certification requirements in Table 2. The organization shall ensure that the applicable requirements of this standard are included within their Quality Management System.

Any significant changes shall be approved by the customer.

For "Production Shop Assist Only" organizations, the applicable elements of AS13100 requirements shall be as defined by the customer, based upon the scope of the work undertaken.

For Supplier types not listed in Table 1 refer to specific Customer requirements.

The flowcharts in Appendix B can be used to illustrate how the requirements of this standard apply to the different Organization Types defined in Table 1 of this standard, see Figure 8 (Hardware Providers), and Figure 9 (Service Providers).

For the Organization Types and how the requirements of this standard apply, see Table 1 and Table 20.

The flowcharts Figure 8 (Hardware Providers) and Figure 9 (Service Providers) in Appendix B can also be used by sub-tier organizations where AS13100 is a contractual flow down.

**Table 1 - AS13100 supplemental requirements applicability**

| AS13100<br>PARAGRAPH<br>REFERENCE | ORGANIZATION TYPE     |                                    |                      |                     |                            |                      |
|-----------------------------------|-----------------------|------------------------------------|----------------------|---------------------|----------------------------|----------------------|
|                                   | TYPE 1: MAKE TO PRINT | TYPE 2A: DESIGN AND<br>MANUFACTURE | TYPE 2B: DESIGN ONLY | TYPE 3: DISTRIBUTOR | TYPE 4: SPECIAL<br>PROCESS | TYPE 5: RAW MATERIAL |
| 4.3.1                             | X                     | X                                  | X                    | X                   | X                          | X                    |
| 4.3.2                             | X                     | X                                  | X                    |                     |                            |                      |
| 4.3.3                             | X                     | X                                  | X                    | X                   | X                          | X                    |
| 4.3.4                             | X                     | X                                  | X                    | X                   | X                          | X                    |
| 4.3.5                             | X                     | X                                  | X                    | X                   | X                          | X                    |
| 4.4.3                             | X                     | X                                  | X                    | X                   | X                          | X                    |
| 5.1.1.1                           | X                     | X                                  | X                    | X                   | X                          | X                    |
| 5.2.1.1                           | X                     | X                                  | X                    | X                   | X                          | X                    |
| 5.3.1                             | X                     | X                                  | X                    | X                   | X                          | X                    |
| 6.1.3                             | X                     | X                                  | X                    | X                   | X                          | X                    |
| 7.1.3.1                           | X                     | X                                  | X                    | X                   | X                          | X                    |
| 7.1.5.1.1                         | X                     | X                                  |                      |                     | X                          |                      |
| 7.1.5.1.2                         | X                     | X                                  |                      |                     | X                          |                      |
| 7.1.5.1.3                         | X                     | X                                  |                      |                     | X                          |                      |
| 7.1.5.1.4                         | X                     | X                                  |                      |                     | X                          |                      |
| 7.2.1                             | X                     | X                                  | X                    | X                   | X                          | X                    |
| 7.2.2                             | X                     | X                                  | X                    | X                   | X                          | X                    |
| 7.2.3                             | X                     | X                                  |                      | X                   | X                          | X                    |
| 7.2.4                             | X                     | X                                  | X                    | X                   | X                          | X                    |
| 7.3.1                             | X                     | X                                  | X                    | X                   | X                          | X                    |
| 7.5.2.1                           | X                     | X                                  | X                    | X                   | X                          | X                    |
| 7.5.3.3                           | X                     | X                                  | X                    | X                   | X                          | X                    |
| 7.5.3.4                           |                       | X                                  | X                    |                     |                            |                      |
| 7.5.3.5                           | X                     | X                                  | X                    | X                   | X                          | X                    |
| 8.1.3.1                           | X                     | X                                  | X                    | X                   | X                          | X                    |
| 8.1.4.1                           | X                     | X                                  |                      | X                   |                            | X                    |
| 8.2.1.1                           | X                     | X                                  | X                    | X                   | X                          | X                    |

**Table 1 - AS13100 supplemental requirements applicability**

| AS13100<br>PARAGRAPH<br>REFERENCE | ORGANIZATION TYPE     |                                    |                      |                     |                            |                      |
|-----------------------------------|-----------------------|------------------------------------|----------------------|---------------------|----------------------------|----------------------|
|                                   | TYPE 1: MAKE TO PRINT | TYPE 2A: DESIGN AND<br>MANUFACTURE | TYPE 2B: DESIGN ONLY | TYPE 3: DISTRIBUTOR | TYPE 4: SPECIAL<br>PROCESS | TYPE 5: RAW MATERIAL |
| 8.2.2.1                           | X                     | X                                  | X                    |                     | X                          | X                    |
| 8.2.3.3                           | X                     | X                                  | X                    | X                   | X                          | X                    |
| 8.3.1.1                           |                       | X                                  | X                    |                     |                            |                      |
| 8.3.2.1                           |                       | X                                  | X                    |                     |                            |                      |
| 8.3.2.2                           |                       | X                                  | X                    |                     |                            |                      |
| 8.3.2.3                           |                       | X                                  | X                    |                     |                            |                      |
| 8.3.3.1                           |                       | X                                  | X                    |                     |                            |                      |
| 8.3.3.2                           |                       | X                                  | X                    |                     |                            |                      |
| 8.3.3.2.1                         |                       | X                                  | X                    |                     |                            |                      |
| 8.3.3.3                           |                       | X                                  | X                    |                     |                            |                      |
| 8.3.4.2                           |                       | X                                  | X                    |                     |                            |                      |
| 8.3.4.3                           |                       | X                                  | X                    |                     |                            |                      |
| 8.3.4.4                           |                       | X                                  | X                    |                     |                            |                      |
| 8.3.4.5                           |                       | X                                  | X                    |                     |                            |                      |
| 8.3.4.6                           |                       | X                                  | X                    |                     |                            |                      |
| 8.3.5.1                           |                       | X                                  | X                    |                     |                            |                      |
| 8.3.5.2                           |                       | X                                  | X                    |                     |                            |                      |
| 8.3.5.3                           |                       | X                                  | X                    |                     |                            |                      |
| 8.3.5.4                           |                       | X                                  | X                    |                     |                            |                      |
| 8.3.6.1                           |                       | X                                  | X                    |                     |                            |                      |
| 8.4.1.2                           | X                     | X                                  |                      |                     | X                          |                      |
| 8.4.1.3                           | X                     | X                                  |                      |                     | X                          |                      |
| 8.4.1.4                           | X                     | X                                  |                      | X                   | X                          |                      |
| 8.4.2.1                           | X                     | X                                  | X                    | X                   | X                          | X                    |
| 8.4.2.2                           | X                     | X                                  |                      | X                   | X                          | X                    |
| 8.4.2.3                           | X                     | X                                  |                      | X                   |                            | X                    |
| 8.4.2.4                           | X                     | X                                  | X                    | X                   | X                          | X                    |
| 8.4.2.5                           | X                     | X                                  | X                    |                     |                            | X                    |



**Table 1 - AS13100 supplemental requirements applicability**

| AS13100<br>PARAGRAPH<br>REFERENCE | ORGANIZATION TYPE     |                                    |                      |                     |                            |                      |
|-----------------------------------|-----------------------|------------------------------------|----------------------|---------------------|----------------------------|----------------------|
|                                   | TYPE 1: MAKE TO PRINT | TYPE 2A: DESIGN AND<br>MANUFACTURE | TYPE 2B: DESIGN ONLY | TYPE 3: DISTRIBUTOR | TYPE 4: SPECIAL<br>PROCESS | TYPE 5: RAW MATERIAL |
| 8.4.2.6                           | X                     | X                                  | X                    | X                   | X                          | X                    |
| 8.4.3.1                           | X                     | X                                  |                      |                     | X                          | X                    |
| 8.5.1.1.1                         | X                     | X                                  |                      |                     |                            | X                    |
| 8.5.1.2.1                         | X                     | X                                  | X                    |                     | X                          | X                    |
| 8.5.1.4                           | X                     | X                                  |                      |                     | X                          | X                    |
| 8.5.1.5                           | X                     | X                                  |                      |                     | X                          |                      |
| 8.5.1.6                           | X                     | X                                  |                      |                     |                            |                      |
| 8.5.1.7                           | X                     | X                                  |                      |                     | X                          |                      |
| 8.5.1.8                           | X                     | X                                  |                      |                     | X                          | X                    |
| 8.5.1.9                           | X                     | X                                  |                      | X                   | X                          | X                    |
| 8.5.2.1                           | X                     | X                                  |                      |                     |                            | X                    |
| 8.5.4.1                           | X                     | X                                  |                      | X                   | X                          | X                    |
| 8.5.6.1                           | X                     | X                                  | X                    |                     | X                          | X                    |
| 8.6.1                             | X                     | X                                  |                      |                     | X                          | X                    |
| 8.7.1.1                           | X                     | X                                  |                      |                     | X                          | X                    |
| 9.1.1.1                           | X                     | X                                  |                      |                     | X                          | X                    |
| 9.1.1.2                           | X                     | X                                  |                      |                     | X                          | X                    |
| 9.1.1.3                           | X                     | X                                  |                      |                     | X                          | X                    |
| 9.1.2.1                           | X                     | X                                  | X                    | X                   | X                          | X                    |
| 9.2.3                             | X                     | X                                  | X                    | X                   | X                          | X                    |
| 9.2.4                             | X                     | X                                  | X                    | X                   | X                          | X                    |
| 9.2.5                             | X                     | X                                  | X                    | X                   | X                          | X                    |
| 9.3.2.1                           | X                     | X                                  | X                    | X                   | X                          | X                    |
| 9.3.3.1                           | X                     | X                                  | X                    | X                   | X                          | X                    |
| 10.2.3                            | X                     | X                                  | X                    | X                   | X                          | X                    |
| 10.2.4                            | X                     | X                                  | X                    | X                   | X                          | X                    |
| 10.3.1                            | X                     | X                                  |                      | X                   | X                          | X                    |

- 4.3.2 Organizations whose products are deliverable software, or contain deliverable software, shall comply with 9115 when planning and evaluating the software design, development, or management activities of the organization.
- 4.3.3 The organization shall be certified by an industry recognized and accredited QMS Certification body for the associated scope(s) of work in accordance with Table 2.

The organization shall cascade these certification requirements to its suppliers in accordance with Table 2.

For National Aerospace and Defense Contractors Accreditation Program (Nadcap) Certifications, the accreditation is administered by the Performance Review Institute (PRI).

- 4.3.4 The organization shall provide access to relevant data within Online Aerospace Supplier Information System (OASIS) and Nadcap databases (e.g., registration documentation, certification, audit reports and findings, corrective actions) to its customers.
- 4.3.5 The organization shall conduct an AS13100 Compliance self-assessment to ensure that the scope of its Management System includes the full scope of this standard, see RM13009 for recommendations on how to complete a compliance self-assessment.

The results of this AS13100 Compliance self-assessment review shall be kept up to date and provided to the customer on request.

The organization shall identify any compliance gaps that they are unable to address and bring these to the attention of the customer for resolution.

**Table 2 - QMS certification requirements**

| ORGANIZATION TYPE                                                                                                                                                                                                                                                                                                          | QMS APPROVAL (MINIMUM REQUIREMENT)                                                         |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------|
| Type 1: Make to Print and Type 2A: Design and Manufacture.<br><br>Manufacture, inspect, test, and certify the conformance of semi-finished and/or finished products (installed on aerospace engines or a component of such a product) to proprietary engineering drawings whether customer design, or organization design. | 9100 registration.                                                                         |
| Type 2B: Design only.<br><br>Contracted Design Responsible Organization/Partner/Supplier Tasks Organizations.                                                                                                                                                                                                              | As defined by Customer's requirements.                                                     |
| Type 3: Distributor.                                                                                                                                                                                                                                                                                                       | 9120 registration.                                                                         |
| Type 4: Special Process (2.3).<br><br>As part of an Organizations manufacturing scope and/or Special Process Houses.                                                                                                                                                                                                       | Nadcap or Customer's requirements.                                                         |
| Type 5: Raw Material.<br><br>Manufacture, inspect, test, and certify the conformance of Raw Material to proprietary engineering specifications.                                                                                                                                                                            | ISO 9001 registration.                                                                     |
| Production Shop Assist Only.<br><br>Offload of planned manufacturing operations.                                                                                                                                                                                                                                           | Per Organizations Requirements based upon scope of work, unless specified by the customer. |
| External Calibration or Laboratory Service Provider.                                                                                                                                                                                                                                                                       | ISO/IEC 17025 or National Equivalent, e.g., UKAS, COFRAC, NIST.                            |
| Industry Standard Part or Industry Standard Raw Material Manufacture.                                                                                                                                                                                                                                                      | ISO 9001 registration.                                                                     |
| Castings and Forgings Produced to a Proprietary Design.                                                                                                                                                                                                                                                                    | 9100 registration.                                                                         |

#### 4.4 Quality Management System and Its Processes

##### 4.4.1 Reference 9100D:09/2016 requirements.

##### 4.4.2 Reference 9100D:09/2016 requirements.

##### 4.4.3 Quality Management System and its Processes - Supplemental Requirements

The organization's Quality Management System shall include Management of Human Factors in its processes (5.1.1.1) including:

- Training of employees.
- An open reporting culture, encouraging the sharing of mistakes without fear of retribution.



- Considering Human Factors in investigations.
- Considering Human Factors in the reporting of performance and identifying improvement plans.

Human Factors should be an integrated part of product and service design, manufacturing/assembly, and product servicing.

NOTE: For details on the deployment of Human Factors within the organization, see RM13010.

## 5. LEADERSHIP

### 5.1 Leadership and Commitment

#### 5.1.1 General

Reference 9100D:09/2016 requirements.

##### 5.1.1.1 General - Supplemental Requirements

Top Management shall demonstrate a commitment to Human Factors in accordance with 4.4.3 and 7.3.1, see RM13010.

#### 5.1.2 Customer Focus

Reference 9100D:09/2016 requirements.

### 5.2 Policy

#### 5.2.1 Establishing the Quality Policy

Reference 9100D:09/2016 requirements.

##### 5.2.1.1 Establishing the Quality Policy - Supplemental Requirements

The organization shall have a policy that includes Human Factors which promotes:

- Open Reporting.
- Continually improving the maturity of Human Factor deployment within the organization.

#### 5.2.2 Communicating the Quality Policy

Reference 9100D:09/2016 requirements.

### 5.3 Organizational Roles, Responsibilities, and Authorities

Reference 9100D:09/2016 requirements.

#### 5.3.1 Organizational Roles, Responsibilities, and Authorities - Supplemental Requirements

Personnel responsible for conformity to product requirements shall have the authority to stop and correct quality problems.

Where the process design prevents immediate shutdown upon detection of a quality problem, then the product or service shall be contained so that it is prevented from being delivered to the customer.

Where production is run across different shifts there shall be personnel identified that are accountable for ensuring conformity to product requirements.

## 6. PLANNING

### 6.1 Actions to Address Risks and Opportunities

6.1.1 Reference 9100D:09/2016 requirements.

6.1.2 Reference 9100D:09/2016 requirements.

#### 6.1.3 Actions to Address Risks and Opportunities - Supplemental Requirements

The organization shall implement a risk management process, e.g., ISO 31000, across their organization and put appropriate governance in place such that they:

- Carry out a robust assessment of risks, in particular those that could threaten future performance, and detail these in a risk register.
- Carry out a review of the effectiveness of their risk management system (including internal controls), at least annually.
- Ensure appropriate risk mitigation is in place (including internal controls) that is appropriate to the risks identified.

The organization shall establish a crisis management and business continuity plan and inform its customer purchasing representative within 3 working days of becoming aware of an issue regarding the following:

- Major incidents affecting the organization that impact the organizations ability to meet customer commitments.
- Risks that could impact the continuity of the organization's business/operations, particularly single points of failure.
- Changes to third party or other party QMS Certification including, lapse/withdrawal/major audit findings to the relevant customer.
- Change of the nominated quality representative, (usually the most senior Quality Leader within the organization).
- Significant change to the Quality Management System.
- Change in ownership or discontinuation of business activities.
- Significant issues of breaches of Information Technology (IT) security systems (Cyber Security).
- Risks with the supply of substances used in the production or physical make-up of products, due to laws and regulations concerning the control or use of such substances that may be published from time-to-time.

### 6.2 Quality Objectives and Planning to Achieve Them

6.2.1 Reference 9100D:09/2016 requirements.

6.2.2 Reference 9100D:09/2016 requirements.

### 6.3 Planning of Changes

Reference 9100D:09/2016 requirements.