ITT

ITT ENIDINE INC

FLIGHT / PRIMARY / SAFETY CRITICAL PARTS PROGRAM MANUAL

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SIGNATURES OF APPROVAL

Electronically Approved in Q-Pulse

REVISION HISTORY

Date:	Revision:	Description:	By:
2/8/08	NONE	INITIAL RELEASE	J.M. Konieczny
11/18/10	A	Review and revised manual as necessary	J.M. Konieczny
4/2/15	B	Added section for criticality designation and COTS parts.	J.M. Konieczny
12/23/15	C	Added section 2.0 Item (11)	C. Robertson
12/12/18	D	Added Primary Parts to the procedures	M. Downing and E. Krajewski
2/18/19	E	Revised section 8.0 regarding rework	E. Krajewski
10/07/20	F	Added definition of an Experimental Safety Item Added section 11.0 Experimental Safety items	M. Abdulla

Statement:

ITT Enidine Inc a subsidiary of ITT Corporation is an FAA PAH and PMA parts manufacturer. Enidine maintains a Quality Management System registered to AS9100. All applicable Enidine Inc. Quality Management System procedures apply to the manufacture of all aviations parts and components including those deemed Flight, Primary, or Safety Critical.

The purpose of this manual is to outline the additional requirements necessary to ensure the quality and integrity of parts and components manufactured for Flight, Primary, or Safety Critical applications.

The requirements outlined in this manual pertain to the final part or product. Sub-assemblies, individual components and hardware should be controlled at a level relative to the criticality of their function in the final part or product. This should be jointly determined by the customer and ITT Enidine Engineering.

Flight/Safety Critical Requirements checklist form no. FM0803141000 can be used as a guide to insure requirements are met and determine the method to comply.

Definitions:

Flight Critical Part:

Any aircraft part, assembly, or installation containing a Critical Characteristic whose failure, malfunction, or absence may cause a catastrophic failure resulting in loss or serious damage to the aircraft or an un-commanded engine shutdown resulting in an unsafe condition.

Safety Critical Part:

Any aircraft part, assembly, or installation containing a Critical Characteristic whose failure, malfunction, or absence may prevent the continued safe operation of the aircraft, or creates an unsafe condition that impacts the safety of the aircraft occupants or flight crew.

Primary Part

An aircraft part, assembly, or installation whose structural integrity is essential for the safety of the aircraft and the failure of which could result in a forced landing of the aircraft. These parts could also be called "Primary Structure." The designation may also cover structural components of installations which would have been critical except for the fact that there is redundancy. The Primary Part designation provides additional control on material traceability to reduce mitigation risk on the manufacturer.

QAM03 Part

Parts identified in our PDM/ERP systems as having additional quality assurance provisions in place.

Criticality Designation

A designation of "Flight Critical" or "Safety Critical" must be made by the customer and clearly stated on all documentation flowed down to ITT Enidine, Inc. ITT Enidine Inc. personnel will not internally make a criticality designation. If a criticality designation has not been made by the customer, the part being produced will not be subject to the requirements outlined in this manual. If it is suspected that the customer failed to flow down a criticality designation, ITT Enidine Engineering will contact the customer to confirm the criticality designation. The customer must provide ITT Enidine Engineering with a written confirmation as to the criticality designation of the part.

Primary Part Designation

A designation of "Primary Part" may either be made by the customer or by ITT Enidine Engineering department. A design manager must agree with the designation. There may be situations where ITT engineering will chose to apply it to gain additional material traceability control. Not all customers have a primary part designation.

Application Review

All flight /safety critical applications shall undergo a complete review between Engineering and the customer. The goal of the review is to fully understand the application and the use of the Enidine product in the application. A DFMEA and PFMEA shall be created and reviewed with the customer prior to production so the customer has a full understanding of the possible modes of failure of the product.

At the time of contract award, a contract review shall be conducted. Compliance matrices shall be prepared to develop the plan for meeting each customer requirement.

Experimental Safety Item

An Experimental Safety Item is a detail or assembly which requires special quality assurance/controls. This designation shall include parts which are non-redundant and failure of which would result in a condition that would inhibit or prevent safe landing, and may also include parts for which structural integrity is essential for the safety of the aircraft and failure of which would result in a forced landing. A designation of "Experimental Safety" may either be made by the customer or by ITT Enidine Engineering department. A design manager must agree with the designation.

2.0 Product Design

Product design shall be based on S.O.P. 4.1.0 Engineering Design and Development, and also incorporate the objectives, principles or techniques, of the fail-safe design concept, which considers the effects of failures and combinations of failures in defining a safe design. The fail-safe design concept uses the following design principles or techniques in order to ensure a safe design. The use of these principles is required to provide a fail-safe design; ***i.e., to ensure that major failure conditions are improbable and that catastrophic failure conditions are extremely improbable.***

(1) Design Integrity and Quality, including Life Limits, to ensure intended function and prevent failures.

(2) Redundancy to enable continued function after any single (or other defined number of) failure(s). See Primary Part.

(3) Component independence where applicable so that the failure of one does not cause the failure of another.

(4) Proven Reliability via design validation to ensure that multiple, independent failures are unlikely to occur during the same flight cycle.

(5) Failure Indicator to provide detection of a failed component or item.

(6) Checkability: the capability to check a component's condition at any point within its life cycle.

(7) Designed Failure Effect Limits, including the capability to sustain damage, to limit the safety impact or effects of a failure.

(8) Designed Failure Path to control and direct the effects of a failure in a way that limits its safety impact.

(9) Margins or Factors of Safety to allow for any undefined or unforeseeable adverse conditions.

(10) All drawings and documents created must be stamped as follows: **"Flight Critical"** or **"Safety Critical"** or "**Primary Part**".

(11) All Item Masters released by engineering which are flight critical, safety, primary, or any derivation thereof shall receive "QAM03" as the first text in the Part Description and Material Description fields. These designations will then be followed by typical part, assembly, or material description; reference controlled document, "SmarTeam Engineering Training".

(12) All Materials and Special Processes shall be called out to a recognized standard on the drawing or item description. All Special Processes shall be called out on the drawing or item description as requiring a NADCAP approved supplier. For "**Flight Critical**" parts, the component parts and special processes will be Vendor Controlled on the applicable drawing or item description.

(13) A DFMEA and PFMEA must be completed. The FMEA's must be reviewed with the customer so they understand the types of failures that could occur. A Safety Analysis must also be performed prior to design release. Product Warnings shall also be established if required.

(14) The final packaging of the product must be established and specified on the Bill of Materials to insure adequate protection during shipment.

(15) If required, an Installation and Maintenance Manual or Instruction Sheet shall be created for the finished good to prevent damage to the product during installation and define any maintenance requirements and intervals.

3.0 Prototypes

Prototypes are intended for ITT Enidine Inc development testing, evaluation, fit up or demonstration. Parts supplied prior to Qualification Testing shall be considered Prototype. Prototype items may only be delivered to external customers for the purpose of bench test, evaluation or mock-up. ***These activities should be verified with the customer.***

Any items intended for flight testing shall not be processed as prototype. All prototype parts for internal use or for delivery to external customers must be marked or labeled as indicated below. If it is not possible to mark the part due to size limitations, the packaging containing the part must be marked or labeled as indicated below:

ITT ENIDINE INC PROTOTYPE
NOT FOR FLIGHT
P/N XXXXXXX
Serial No. XXXXX
(Additional marking as required – verify with ITT Enidine FAA Compliance and the customer.)

4.0 Product Qualification

Prior to the implementation of production of any part deemed flight/safety critical, the product must be qualified to insure it meets all applicable requirements. Qualification is done by establishing a Qualification Plan with the Compliance Matrices. Qualification activities may include flight testing to verify design parameters and airworthiness.

After approval from the customer, a Qualification Procedure is established and approved by the customer. A Qualification Test Report must then be generated and approved by the customer. ***These activities should be verified with the customer.*** Qualification activities may be performed concurrently with aircraft type certification activities. Items intended for flight testing must be marked or labeled as indicated below. If it is not possible to mark the part due to size limitations, the packaging containing the part must be marked or labeled as indicated below:

ITT ENIDINE INC
FOR FLIGHT TEST
P/N XXXXXXX
Serial No. XXXXX
(Additional marking as required – verify with ITT Enidine FAA Compliance and the customer.)

Parts used for flight test, qualification or type certification activities must be marked as such to avoid mistaking them for new and unused parts should the aircraft undergoing type certification is later refurbished and sold.

5.0 Process Validation / Process Control

Prior to the implementation of production of any part deemed flight/safety critical, all manufacturing processes must be validated to ensure they are repeatable and capable of producing products that meet or exceed all applicable performance and safety requirements. Upon completion of the validation activities, a manufacturing process map will be generated depicting the process elements and process flow.

The process map must be revision controlled. When specified by contract, the applicable customer must be notified and approve all process changes. All process changes will require a complete revalidation to ensure the process remains repeatable and capable of producing parts that meet or exceeds all applicable performance and safety requirements. Once these activities are complete, the process map will be rolled to the next revision. All changes must be approved by Design Engineering, Manufacturing Engineering, Manufacturing and Quality Assurance.

Adequate and necessary controls must be put in place to maintain the integrity and repeatability of each process. Suitable means to adjust and monitor the process to maintain repeatability and integrity and product quality need to be established. A control plan depicting the monitoring and control points for the process will be generated and revision controlled. All changes must be approved by Design Engineering, Manufacturing Engineering, Manufacturing and Quality Assurance.

6.0 Identification and Traceability

Part Marking

All parts deemed flight or safety critical must be identified properly. At a minimum, parts will be marked with the Enidine, Inc. name, item part number, and serial number. Additional marking per customer requirements or Enidine practice for that part type can be added. In addition, parts/components that have achieved PMA must be marked **FAA-PMA.**

Serialization

Flight Critical parts deemed replaceable must be serialized. This means parts that are complete and can be replaced individually on the aircraft. This does not pertain to individual components that make up the completed flight critical part. See Enidine Inc. S.O.P. 4.6.1. for serialization instructions. All serialized parts must be accounted for. No serial number may be duplicated. All serialized parts that are scrapped after final inspection must be recorded and noted on the production router and serial number log. ***Note: This section pertains only to the final product or critical components of a final product. It does not include non-critical components or hardware.***

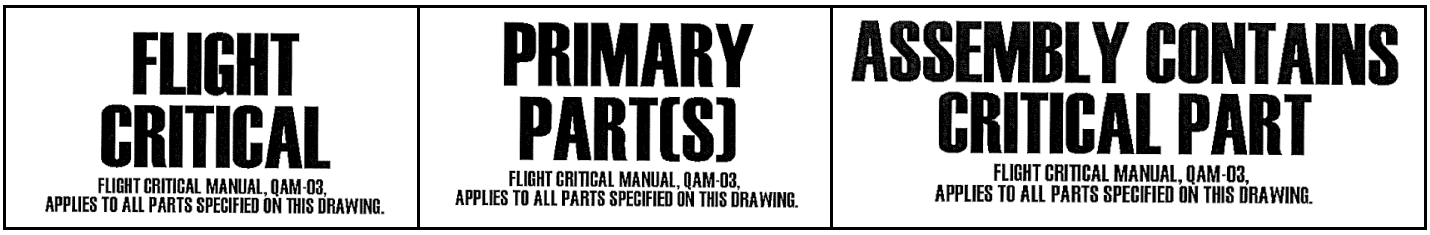
Primary Parts may also be serialized and the method and location of serialization shall be specified on the drawing. The difference between Critical and Primary Parts is that the traceability of primary can be tracked by production routers and manufacturing records. The top assembly must contain a note “This assembly contains a Primary Part”. The top assemblies of Primary Parts shall be serialized if the Primary Parts are serialized.

Material Traceability

All parts deemed Flight, Primary, or Safety Critical require complete material traceability. Raw materials from which build to print parts are produced will require Certified Material Test Reports (CMTR) and individual lot traceability. All Special Processes such as plating, heat treating, passivation, etc. require Certificates of Compliance from each respective processor attesting that the special process was performed and successfully completed to the applicable standard or requirement. Lot numbers of all components that make up the final part or assembly must be recorded on the production router and maintained for each serialized production lot.

Production

All documents issued for production must be stamped **"Flight Critical"**, **"Safety Critical"**, or "**Primary Part**" as identified by ITT Enidine and the customer.



Production routers must detail each sequence in the manufacturing process. The production router must also list the serial number range, if applicable, and quantity of the parts to be completed. As each sequence is completed, it must be signed off by the individual responsible for the completion of that sequence.

Prior to final inspection, Quality Control will verify that all production sequences have been completed. Final inspection may only commence upon verification that all production sequences have been signed off. A production lot will be rejected and quarantined as suspect material if all sequences are not signed off on the production router.

7.0 Inspection and Test

An Inspection Plan must be established for all inspection activities listed below.

Incoming Materials

All procured materials/items used in the manufacture of **QAM03** parts must undergo incoming inspection **(see Commercial off the Shelf COTS note)** performed by Enidine personnel or outside approved 3rd party accredited sources. . **NO PROCURED MATERIALS/ITEMS MAY GO DOCK TO STOCK!**

At a minimum, incoming inspections will be performed to Enidine S.O.P. 5.2.1. "Sampling Inspection and Lot Sampling" at a 99% reliability level. If specified by contract, a customer supplied inspection plan must be used per the instructions outlined in the plan.

In-Process Inspection

At a minimum, in-process inspections will be performed to Enidine S.O.P. 5.2.1. "Sampling Inspection and Lot Sampling" at a 99% reliability level. If specified by contract, a customer supplied inspection plan must be used per the instructions outlined in the plan.

First Article Inspection

First Article Inspection will be performed per the requirements of AS9102, Enidine S.O.P. 5.3.3., and individual customer requirements and must be performed by Enidine Personnel or outside approved 3rd party accredited sources.

Final Inspection

Finished parts designated "**Flight Critical"** will be 100% inspected unless otherwise specified by customer

contract.

Finished parts designated "**Safety Critical"** or **"Primary Part"** at a minimum will be inspected per Enidine S.O.P. 5.2.1., "Sampling Inspection and Lot Sampling" at a 99% reliability level, unless 100% inspection is specified by customer contract. All Key (or critical) part characteristics will be inspected 100%. Key characteristics must be identified in the appropriate inspection plan for the part.

Design Engineering is to identify key characteristics, provide the information to Quality Control and approve the completed inspection plan defining these characteristics. All inspection activity will be recorded on the inspection plan form created for the part. The inspection results will be recorded by serial number for each unit, the inspector performing the inspection and the date of the inspection.

Acceptance Test

Unless otherwise specified, non-destructive acceptance testing will be performed on **QAM03** parts per a customer approved Acceptance Test Procedure (ATP) for the finished part at the 100% level. Acceptance Test Data shall be recorded and tied to the serial number who performed the test, and the test date.
Destructive testing will be performed per the specified ATP and sample size. The appropriate level of testing will be determined by Design Engineering and Quality following design validation, or specified by the customer. The test results will be recorded by serial number for each part, the technician performing the test and the test date.

8.0 Control of Non-Conforming Product

In-House Rejected Material

Any material, part or component rejected during an inspection or test operation must be clearly identified as **QAM03 Rejected Material**, tagged and physically removed from the area or accepted product stream and placed in the designated quarantine area for flight /safety critical parts. The material cannot be removed until disposition has been completed by the appropriate authorities.

Returned Product

Product returned as non-conforming must be clearly identified as **QAM03 Rejected Material** tagged, and placed in the designated quarantine area for flight/safety critical parts. The product cannot be removed until disposition has been completed by the appropriate authorities.

ITT ENIDINE Inc. shall promptly notify the customer when a nonconformity is discovered in materials or products that may affect the integrity or safety of product already delivered. Such notification shall include a description of the non-conformance, product(s) affected (part number, serial number, lot number, quantity and manufacturing dates where applicable).

Rework of Rejected Material/Product

Product requiring rework must be segregated from acceptable product and identified as non-conforming.
Rework requires specific instructions as to the nature of the rework to be performed. When applicable, these instructions need to be approved by the customer prior to the rework. Rework and verification instructions shall be performed on the originally issued work order associated with the part, if this is not feasible or the rework product is not easily identified from accepted product, a special production router shall be created for the specific non-conforming material/product. The rework process must be approved in accordance with SOP 5.3. All rework sequences need to be signed off by the individual responsible for completing that sequence.

All appropriate inspection and test operations must be performed and their results documented and approved by the appropriate authorities.

Material/Product Designated as Scrap

Material/Product designated as scrap must be handled as follows:

- Material and Individual components that make up a finished product shall be scrapped per Enidine, Inc. S.O.P. 5.3.
- Finished Product must be tagged as scrap, removed from the production area and quarantined.
- For finished product, the serial number must be recorded. (See Section 10.0 Records)
- All **finished product** must be **mutilated** prior to discarding it to prevent unauthorized installation on a type certificated aircraft or engine.

FAA Notification

ITT Enidine INC. will notify the FAA immediately should any part or component be identified that could result in an unsafe condition, or should any part or component not meet the applicable airworthiness requirements.

ITT Enidine INC. will report to the FAA the results of all investigations and findings with regard to the parts or appliances in question, and report the actions taken and proposed.

ITT Enidine INC. will also submit to the FAA Administrator all information necessary to implement the corrective action or actions needed for the safe operation of the part or component. Notification of any unsafe part or component will be made in writing to the Administrator, unless it is deemed to be a critical safety issue, Critical safety issues will be handled by phone notification to the FAA, with a follow up letter to the Administrator.

9.0 Procurement of Materials

Materials, parts, components, and outside services provided by processors may only be procured from suppliers who:

- Are listed on the Enidine, Inc. "Approved Suppliers List".
- Are 3rd Party Accredited (ISO9001:2000, AS9100, etc.)

Note: If a supplier must be used who is not 3rd Party accredited, ITT Enidine Inc Quality Assurance must conduct an onsite audit of the supplier's manufacturing facility. The audit is to ensure that the supplier has the capabilities and necessary systems in place to produce and deliver parts that are airworthy and conform to all requirements. Upon completion of the audit, QA, Engineering and Compliance will review the audit report. The supplier will be approved or denied based on the audit results.

- Suppliers who provide special processes, heat treat, plating, passivation, etc. must be NADCAP approved for the process they are providing.
- Certified Material Test Reports (CMTR) must be provided for all raw materials and for raw material batches from which individual components are produced.
- Processors must provide Certificates of Compliance attesting that the special process was performed and successfully completed to the applicable standard or requirement.
- Suppliers must provide Certificates of Compliance and copies of their final inspection reports for each lot of material or components supplied.
- For "**Flight Critical"** Parts the component parts and special processes will be Vendor Controlled on the applicable drawing or item description.

IMPORTANT: These requirements also apply to sub tier suppliers and must be flowed down to sub tier suppliers when applicable.

Note: All procured materials/items used in the manufacture of Flight Critical or Safety Critical Parts/Components that provide a critical function in relation to the design, performance or functional integrity of the critical part must undergo incoming inspection by Enidine Personnel.

Note: In cases where ITT Enidine Engineering has determined that a COTS item does not provide a critical function in relation to the design, performance or functional integrity of the critical part, the COTS item may be utilized in the same manner as those used for standard product are not subject to the requirements of this manual.

10.0 Records

The following records must be maintained for QAM03 components and their assemblies:

- Design Drawings, Design Validation Records.
- Process Validation, Process Control Maps and Control Plans.
- Serial number log for all finished product.
- Scrap log for all serialized product scrapped.
- CMTR, C of C for all procured components traceable to each production lot of finished product.
- Supplier Inspection Reports traceable to each lot of supplied material or components.
- Incoming, In-Process, Final Inspection Reports.
- ATP test results.
- Completed Production Routers traceable to each production lot of finished product produced.
- Non-conforming material reports/rejection reports.
- First Article Inspection Reports (FAI).
- Additional documents required by customer contract.

RECORDS MUST BE RETAINED FOR A MINIMUM OF 30 YEARS PER SOP 1.2 CONTROL OF RECORDS, WHICHEVER IS LONGEST.

After completion of final inspection, the router shall have a sequence routing all documents to QA for review of the entire document package and approval, and electronic storage.

11.0 Experimental Safety Items

This section establishes the requirements for supplier control, management, planning and traceability of items which engineering designates as “Experimental Safety Item”.

11.1 Program Administration

Raw material, sub-tier manufacturing and special process sources for Experimental Safety Items shall be supplied with this document. Purchase orders shall have clear notation of the item’s designation (“Experimental Safety Item”) along with reference to this section (QAM-03 Section 11.0)

In addition, all documents applicable to Experimental Safety Items (i.e. manufacturing, processing, procurement, quality, shipping, etc.) shall have clear notation of the item’s designation (“Experimental Safety”). In cases where a standard form is being used and “Experimental Safety Item” cannot be checked it is permissible to hand-write or otherwise designate “ESI” on documentation.

11.2 Part Nomenclature

Part description shall begin with “QAM03, EXPERIMENTAL SAFETY ITEM” to ensure that all documents applicable to Experimental Safety Items (i.e, manufacturing, processing, procurement, quality, shipping, etc.) have clear notation of the item’s designation (“Experimental Safety Item”).

11.3 Identification and Traceability

Serialization

All Experimental Safety Item shall be serialized in accordance with the following:

A. The part marking and location of serialization shall be specified on the drawings.

B. The marking method shall be permanent except where prohibited by physical or functional attributes. When physical or functional attributes prohibit permanent physical serialization, each Experimental Safety Item must be otherwise identified with a serial number and documented.

C. Experimental Safety Item assemblies and installations may or may not require serialization as defined on the drawings.

Production

All documents issued for production must be stamped **“Experimental Safety Item”**

Production routers must detail each sequence in the manufacturing process. The production router must also list the serial number range, if applicable, and quantity of the parts to be completed. As each sequence is completed, it must be signed off by the individual responsible for the completion of that sequence.

Prior to final inspection, Quality Control will verify that all production sequences have been completed. Final inspection may only commence upon verification that all production sequences have been signed off. A production lot will be rejected and quarantined as suspect material if all sequences are not signed off on the production router.

11.4 Approved Manufacturing/Process Planning

A written plan in English outlining applicable manufacturing, processing, inspection, assembly or Installation operation/process resulting in an experimental safety item shall be created by the entity manufacturing the part (ITT or sub-tier) and approved by the customer prior to first delivery of an experimental safety item. Package shall be comprised of manufacturing operation sequence, inspection checksheet(s), sketches and any other applicable data to demonstrate method of manufacturing.

After initial Planning Review Team approval, the detailed written manufacturing planning, the product traveler and the Inspection Check Sheet shall not be changed without re-approval by the customer. Any changes to the documents must be submitted for approval except when changes are due to the following:

- Updated engineering revision status having no impact on product being controlled by planning,
- Relocation from one piece of equipment of the same manufacturing type, to another location, providing the change in location does not alter the initially approved manufacture planning package or does not alter the programming, tooling, methodology, etc. (Changing from one method of manufacturing to another is not permissible without prior approval through the applicable PRT or ECM approving Redline)
- Addition of inspection sequences,
- Revised or changed tooling identification,
- Relaxed tolerance dimensioning when authorized by Engineering,
- Tightened tolerance dimensioning,
- Typographical errors,
- Minor dimensional machining revisions of planning to semi-finished attributes to allow for clean up or to compensate for process (including tooling) variation.

Customer approved manufacturing or process planning documents should be annotated as “APPROVED”.
Approved plan shall clearly note that any changes shall be approved by the customer.
The customer shall be notified in writing of each planning document’s initial release and subsequent revision thereof either in writing to the applicable customer Buyer. Notification to include the following as a minimum:

- Supplier name & location
- Customer Supplier Code
- Customer Part Number
- Customer Drawing & Parts List Revision
- Supplier Part Number – Where applicable
- Supplier Drawing Number – Where applicable
- Supplier Drawing Revision – Where applicable
- Supplier Planning Revision & Date (MM-DD-YY)
- Supplier Inspection Check Sheet Revision & Date (MM-DD-YY)
- Supplier’s manufacturing plan shall reflect the following as a minimum: Notation of designation on planning document, i.e. “Experimental Safety Item”. Manufacturer's name and location.
- Planning Revision History Record Sheet showing initial release and reason for subsequent revisions.
- Part number, complete with dash number.
- The Drawing revision letter, Parts List revision level.
- The material used, including the applicable specification numbers, and provisions for verification of the correct material by Supplier inspection personnel. When an assembly, the identification of each Experimental Safety Item part number contained within the assembly.
- Sequential manufacturing, processing, test, and inspection operations, including sequencing options, with provisions for indicating acceptance or rejection and date of accomplishment for each operation.
- Provisions for recording traceability/serial-numbers