GENERAL DYNAMICS Ordnance and Tactical Systems	REVISION DATE 07/29/2020	NUMBER QS-GD-10.7.1
	Rockets Business Unit	
PRE-VALIDATION AND PROCESS CHANGE GUIDE FOR SUPPLIERS HYDRA-70 FY20-24	CONTENT LEAD Quality Systems	
	DOCUMENT OWNER Sr. Manager, Quality	

1. PURPOSE

This guidance document provides information to suppliers working with General Dynamics Ordnance and Tactical Systems, Inc. (GD-OTS) for the processes needed to navigate the various validations that will need to be performed in support of the FY20-24 Hydra-70 contract. This information on the validations contains some of the requirements that are flowed through the purchase order to the supplier. The processes include the process change request (PCR) and the pre-validation run. The different validations that can be performed include:

- Baseline Qualification First Article Test (BQFAT)
- First Article Test (FAT)
- Tailored First Article Test (TFAT)

- First Piece Inspection (FPI)
- Internal Validation
- Inspection and Test Equipment (ITE) Validation

2. REFERENCES

Most of the reference documents, forms and templates listed in this section are available in the general Subcontract Management folder on the GD-OTS SharePoint collaboration site. The ones available in other locations will specify the location.

2.1 Reference

Document	
FY20-24 Quality Clauses (Q7xx)	https://www.gd-ots.com/suppliers/resources/hydra_qualityclauses/
QS-GD-10.7.2	Plan and Report Completion Guide
Supplier Bulletins	Quarterly Bulletins (in GD-OTS SharePoint Supplier Bulletins Folder)
BQFAT Lessons Learned	Presentation with Helpful BQFAT Information
Completing AS9102 Forms	Presentation with Helpful Information on AS9102 Forms
ITE-Validation-Execution	Presentation with Helpful Information on ITE Validations
Interpreting Calibration Reports	Presentation with Helpful Information on Calibration Reports

2.2 Forms and Templates

Form / Template	Filename
QS-FM-10.7.1	FY20-24 Process Change Request Form
QS-TP-10.7.1	FY20-24 FAT/TFAT Plan Template
QS-TP-10.7.2	FY20-24 FAT/TFAT Report Template
QS-TP-10.7.3	FY20-24 FPI Plan Template
QS-TP-10.7.4	FY20-24 FPI Report Template
QS-TP-10.7.5	FY20-24 BQFAT Plan Template
QS-TP-10.7.8	FY20-24 ITE Plan Template
QS-TP-10.7.9	FY20-24 ITE Report Template

3. GUIDE

This guide provides a roadmap of how to navigate the validation process. Figure 1 provides a simple flow of the validation process including the process change steps.

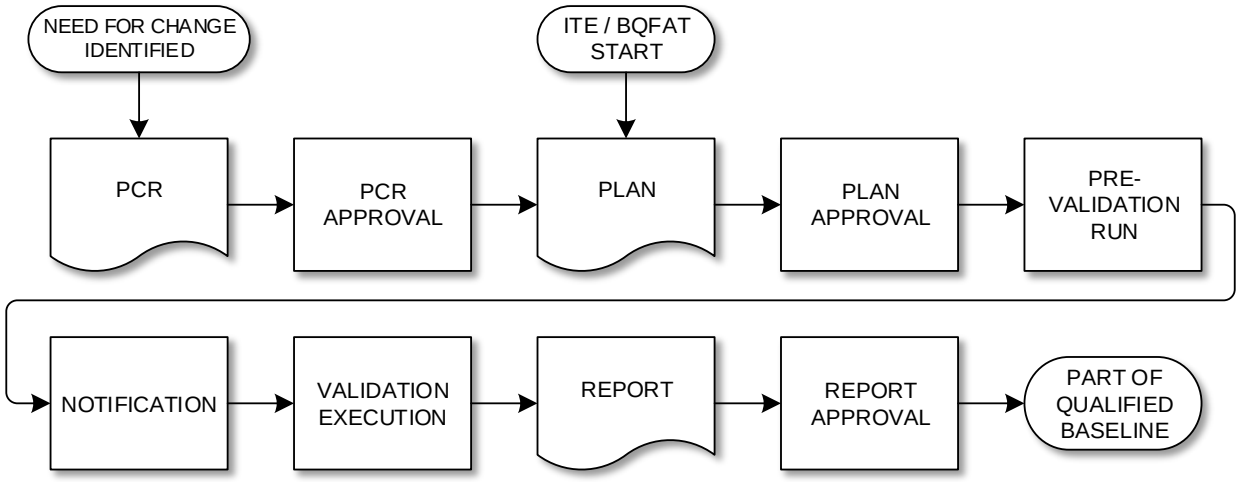


Figure 1. Validation Process Flow

3.1 The Qualified Baseline

The Qualified Baseline is the objective evidence of compliance for a part number to the technical data package (TDP). Quality clauses (Q-clauses) Q720 BQFAT and Q728-1 Pre-Validation Activity provide the requirements for the BQFAT process. Elements that provide objective evidence of the qualified baseline include:

- Approved BQFAT Report
- Master List of Inspection and Test Equipment (If applicable)
- Approved Process Flow
- Approved Process Control Plan (If applicable)
- Any validations approving changes to the qualified baseline
- Any additional baseline information that is unique to a part number

Once the baseline is established, no changes can be made to the processes without following the appropriate steps to have the change approved and validated. Q-clauses Q728 Changes to the Qualified Baseline and Q728-1 Pre-Validation Activity provide the requirements for the change process.

The following table provides the steps for each process and the established review and notification times. The Tactical Aviation and Ground Munitions (TAGM) review cycle time is applicable for each revision of a document. If TAGM responds with comments after the review cycle time (30 days), the document will need to be revised and resubmitted. That revision also goes through the review cycle time (30 days).

Table I. Validation Steps and Times

VALIDATION STEP	BQFAT	FAT/TFAT	FPI	ITE
Submit PCR	N/A	X	X	X[1]
Approve PCR	N/A	TAGM	TAGM	GD
Generate Plan	X	X	X	X
TAGM Review and Approval/Rejection (Days)	30	30	N/A	N/A
Execution of Pre-Validation Run	X	X	X	X
Notification of Validation (Days)	30	30	30	14
Execution of Validation	X	X	X	X
Generate Report (due to GD-OTS x days after completion of validation)	10	10	15	10
TAGM Review and Approval (Days)	30	30	N/A	N/A
TOTAL TIME (Days Minimum)	**100**	**100**	**45**	**24**
TYPICAL TIME (Days Overall)	**147**	**138**	**75**	**59**

[1] The PCR is not required if the ITE validation is part of a BQFAT effort.

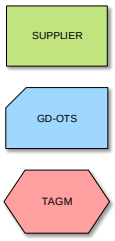
The following forms and templates are available on the GD-OTS Hydra Subcontract Management SharePoint collaboration site. Use these templates for your PCR, Plans, and Reports. Please refer to QS-GD-10.7.2 Plan and Report Completion Guide when using the plan and report templates.

Table II. Validation Forms and Templates

TEMPLATE NUMBER	TYPE OF DOCUMENT	REFERENCED IN Q-CLAUSE	GOVERNMENT CDRL NO.	SUPPLIER SDRL NO.
QS-FM-10.7.1	PCR Form	Q702, Q728, Q728-Alt1	N/A	728A
QS-TP-10.7.1	FAT/TFAT Plan	Q728, Q748	A005	728B
QS-TP-10.7.2	FAT/TFAT Report	Q728, Q748	A013	728E
QS-TP-10.7.3	FPI Plan	Q728, Q748	A014P (Non-CDRL)	728C
QS-TP-10.7.4	FPI Report	Q728, Q748	A014	728F
QS-TP-10.7.5	BQFAT Plan	N/A	A005	N/A
QS-TP-10.7.8	ITE Plan	Q718	X060 (Non-CDRL)	718A
QS-TP-10.7.9	ITE Report	Q718	X061 (Non-CDRL)	718C

For BQFAT, FAT, and TFAT validation planning, the requirement for sample quantities is as follows: Unless otherwise specified in the TDP, sample quantities shall be 25 for Safety, Special, Critical and Major Characteristics, 10 for Minor Characteristics, 2 for Unlisted Characteristics, and 1 for Reference and Basic Characteristics.

The following sections provide an overview of the process change request and validation processes. The process flow charts in these sections use the following flow chart shapes and colors to specify who performs the action:



Supplier Action

GD-OTS Action

TAGM/Government Action

3.2 BQFAT

The BQFAT establishes the baseline as discussed in section 3.1. Figure 2 provides the process flow for the BQFAT validation. The BQFAT validation must use the same processes and equipment, including ITE, that will be used in production. For parts having listed characteristics (Safety, Special, Critical, Major), an ITE validation must be performed prior to the BQFAT. The ITE will then be approved for use for the BQFAT and for production. For ITE validation information, go to section 3.7.

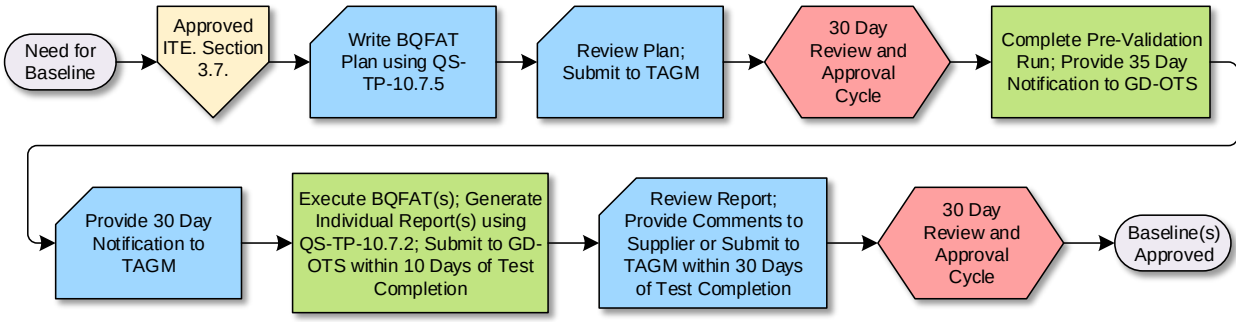


Figure 2. BQFAT Process Flow

Please refer to the presentations "BQFAT Lessons Learned" and "Completing AS9102 Forms" on the SharePoint collaboration site for information on BQFAT completion.

3.3 Pre-Validation

Pre-validation runs (also known as "dry runs") ensure suppliers are adequately prepared for a planned validation with evidence of process success. Pre-validation runs are required to be performed before all validations. The default pre-validation run scope is to perform a full validation run as defined below. However, certain portions of the pre-validation run are tailorable with GD-OTS approval, as noted in Q-clause Q728-1 Pre-Validation Activity. Coordinate any tailoring request with the GD-OTS Supplier Quality Engineer (SQE) and Subcontract Manager.

Table III. Tailorable Pre-Validation Elements

Pre-Validation Element	Tailorable (Y/N)
• Full AS9102 dress rehearsal – Full sample quantities – All characteristics – All associated testing/performance requirements. – All paperwork filled out and in place (AS9102, certifications, etc.)	Y
• GD witnesses the pre-validation run	Y
• Procedures/work instructions available	N
• Control plan complete – Welding/Heat Treat - samples	N
• Process flow complete	N
• Equipment identified and set up where it will be used in production	N

The pre-validation run requirement is flowed to the supplier through Q-clause Q728-1 Pre-Validation Activity. The pre-validation run must replicate the production process that will be used and validated during the BQFAT/FAT/TFAT/FPI.

Data must be provided to GD-OTS after the pre-validation run has been completed. This will be maintained in the Qualified Baseline folder for the specific part number.

A pre-validation run **IS**:	A pre-validation run is **NOT**:
▪ Full dress rehearsal of the validation; ▪ Full sample quantities; ▪ Running parts with production equipment processes, and personnel; ▪ Performing inspections on all characteristics defined in the validation; ▪ Producing parts to ensure validation success; ▪ Ensuring all measurement equipment and techniques are adequate and capable.	▪ Just a review of paperwork; ▪ Making a few parts to make sure the main equipment works; ▪ Walking the production line without parts being run; ▪ Performing inspections only on Critical and Major features.

A validation readiness review checklist is provided in Attachment 1 as a preparation aid for the validation to be performed. This checklist may also be helpful in preparing for the pre-validation run.

3.4 Requesting a Change

The PCR provides the means for a supplier to request a change to a process that has been baselined. Many things drive the request for a change. Some reasons for requesting a change include process improvement, scrap reduction, corrective action implementation, design changes, and many others. Please refer to Q-clause Q728 for the list of reasons for change and reason codes. Attachment 2 provides a list of the Q728 change codes for reference.

The following process flow provides the steps associated with the PCR.

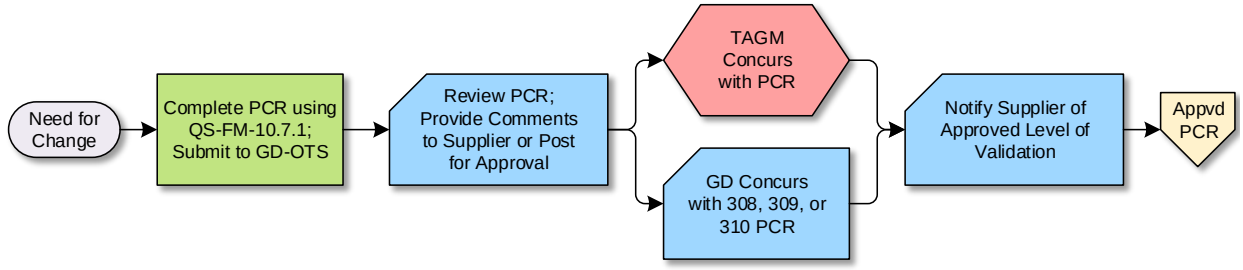


Figure 3. PCR Process Flow

When filling out the PCR form, determine whether the change requires an update to documentation associated with the approved baseline (Process flow maps, process control plans, Process Failure Modes and Effects Analysis (PFMEA), etc.) and identify those documents affected in the PCR section 4. The supplier is required to update the affected documents as required by Q-clause Q728.

3.5 FAT and TFAT

A FAT is similar to a BQFAT; all requirements, including dimensions, material, special processes, and tests, will be covered. For a TFAT, the validation is tailored to focus on a specific process change within the TDP requirements. The FAT and TFAT have the same process flow. The FAT and TFAT require government approval for the plans and reports. FATs and TFATs are typically performed on items with a characteristic classified as Safety, Special, Critical, Major, or Minor.

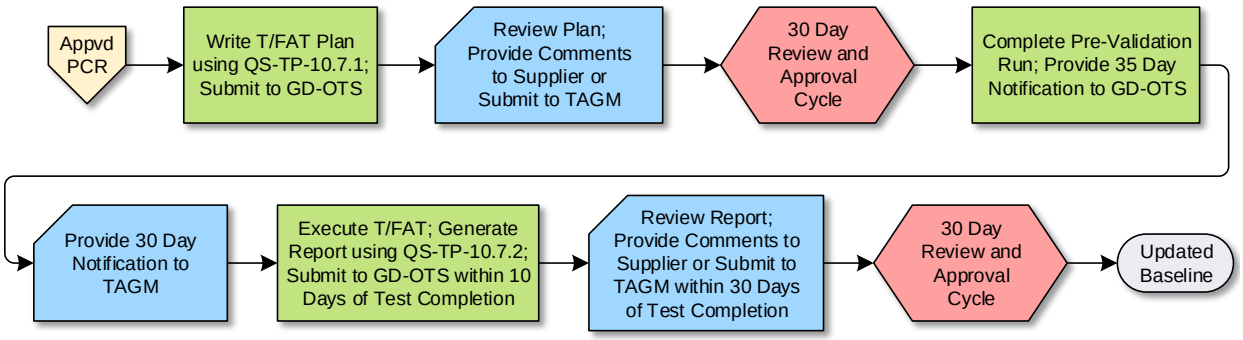


Figure 4. FAT/TFAT Process Flow

Please refer to the presentation "Completing AS9102 Forms" on the SharePoint collaboration site for information on completing the AS9102 forms used as the Master Test List and Data Sheets for the validations.

3.6 FPI

An FPI is similar to a TFAT; the validation is tailored to focus on a specific process change within the TDP requirements. FPIs are typically performed on items without a characteristic classified as Safety, Special, Critical, Major, or Minor or when the change poses a low implementation risk.

Both the FPI plan and report are not approved by the government. So, that cuts out the government review cycle time. However, the report is a data deliverable to the government and must be posted 45 days after completion of the validation. The supplier must submit the report to GD-OTS within 15 days after completion of the validation.

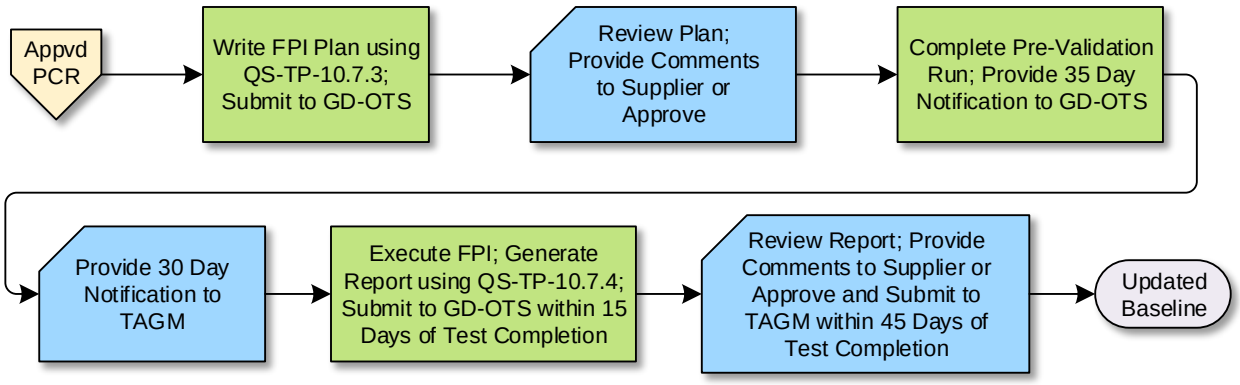


Figure 5. FPI Process Flow

Please refer to the presentation "Completing AS9102 Forms" on the SharePoint collaboration site for information on completing the AS9102 forms used as the Master Test List and Data Sheets for the validations.

3.7 ITE

Suppliers are required to perform ITE validations in accordance with the requirements of Q-clause Q718 Inspection and Test Equipment Validation Plans and Reports. An ITE validation ensures all ITE used to inspect characteristics identified as Safety, Special, Critical or Major is capable of the required accuracy and precision for determining conformance to all technical and contractual requirements. After successful completion of the validation and submission of the report, the ITE will then be baselined in a Master List of ITE for the specified part.

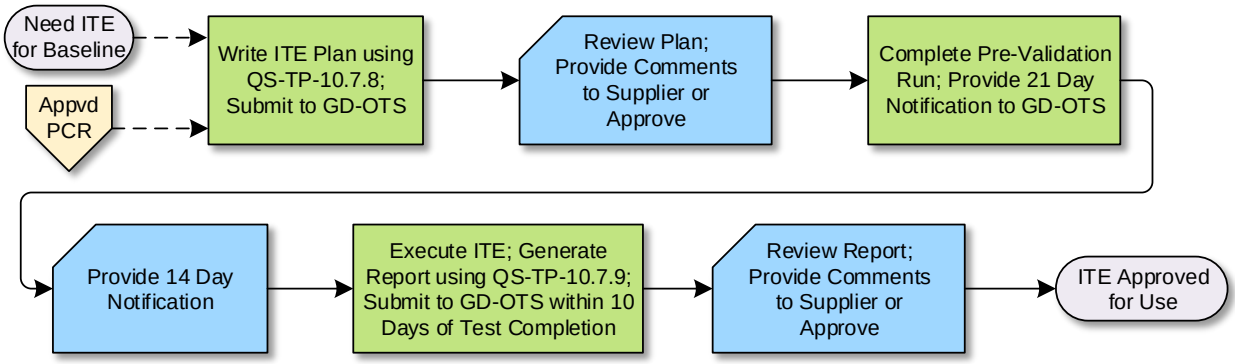


Figure 6. ITE Process Flow

Please refer to the presentations "ITE Validation Execution" and "Interpreting Calibration Reports" for additional information on ITE validations and the gage repeatability and reproducibility studies that are part of it.

3.8 Internal Validation and Validation Not Required

Other validations selections include Internal Validation and Validation Not Required as defined in Q-clause Q728 Changes to a Qualified Baseline. Suppliers need to present all changes to GD-OTS to confirm the level of validation, even if requesting one of these two categories.

Internal Validation

An internal validation is defined as a validation the supplier can perform without preparing a formal plan or report and will not have to provide notification. The supplier does, however, need to retain records of the results of the internal validation and have them available for review upon request.

Validation Not Required

Validation is not required for changes associated with Q-clause Q728 change code 310:

> *310 Minor changes to work instructions that have no effect on the process (i.e. clarification)*

The suppler still needs to submit a PCR to GD-OTS for changes identified as change code 310. If GD-OTS agrees with the code 310 request, GD-OTS will approve the PCR.

In addition, validation is not required for changes associated with Q-clause Q728 change codes 308 and 309:

> *308 Preventative Maintenance or replacement of normal machining wear items (i.e. saw blades, cutting tools, etc.)*
>
> *309 Performing normal machine offsets due to tool wear*

Before proceeding with the activities defined by change codes 308 and 309, please confirm with the GD-OTS SQE or subcontract manager that GD-OTS agrees with the change code. If confirmed, these changes should be documented internally by the supplier making the change.

4. ACRONYMS AND DEFINITIONS

4.1 Acronyms

Acronym	Definition
BQFAT	Baseline Qualification First Article Test
CDRL	Contract Data Requirements List
FAT	First Article Test
FPI	First Piece Inspection
GD-OTS	General Dynamic Ordnance and Tactical Systems, Inc.
ITE	Inspection and Test Equipment
PCR	Process Change Request
PFMEA	Process Failure Modes and Effects Analysis
Q-Clause	Quality Clause
SDRL	Supplier Data Requirements List
SQE	Supplier Quality Engineer
TAGM	Tactical Aviation and Ground Munitions
TDP	Technical Data Package
TFAT	Tailored First Article Test

4.2 Definitions

Term	Definition
BQFAT	A validation performed on a system, subsystem, or component to establish the Qualified Baseline. BQFAT requirements are specified in Q-Clause Q720 and Q728-1. Both the plan and report require government approval.
FAT/TFAT	A validation performed on a system, subsystem, component, material, or specification revision for a change from the Qualified Baseline. The validation is performed on defined TDP characteristics as documented in the prints, specifications, etc. FAT/TFAT requirement are specified in Q728 and Q728-1. These validations are performed with the facilities, production processes, methods, materials, personnel and equipment used for production. Both the plan and report require government approval.
FPI	A validation performed on a system, subsystem, component, material, or specification revision for a change from the Qualified Baseline. FPI requirement are specified in Q728 and Q728-1. These validations are performed with the facilities, production processes, methods, materials, personnel and equipment used for production. Neither the plan nor report require government approval. However, the report is a required data item to be submitted to the government.

Term	Definition
Internal Validation	A validation activity that does not require Government approval or notification. The Supplier performs the internal validation and maintains records of that validation for review, if requested. GD-OTS will ensure the adequacy of its supplier's internal validations.
Pre-Validation Run	A "dress-rehearsal" of a planned validation used to prepare for performance of the actual validation mitigating the potential risk of a failure during that validation.
Qualified Baseline	The baseline of a specified part based upon successful completion of a BQFAT to the TDP requirements, the Master List of ITE, and any validations performed after BQFAT.

5. ATTACHMENTS

Attachment Number	Description	File
1	Validation Readiness Review Checklist	Validation-Readiness-Review-Checklist_
2	Process Change Categories from Q728 *(For Reference Only. Please follow the link to the Q-clause listing in Section 2.1 to review the official Q-clause listing.)*	Process-Change-Codes-Ref_Q728.docx

