



Q728 Changes to a Qualified Baseline (Process Change) **Flowdown to Subcontractors Required
(Rev 07/29/20)**

This clause requires the following SDRL deliverable(s): S728A, B, C, D, E, & F - See Exhibit A for details.

Changing the Qualified Baseline is a formal time consuming process that requires GD-OTS and US Government approvals. All proposed changes should be planned months in advance of required implementation. Seller shall request and receive written GD-OTS approval prior to making any changes that deviate from the qualified baseline (either that qualified in the Baseline Qualification FAT or by subsequent qualified modification). This change requirement shall be applicable to the lowest level of supplier in the supply chain at which the characteristic is generated. Attachment 0012 (included below) contains a listing of changes that require notification and approval. Seller must make a formal request for any such change. Seller's request for such a change shall be formally submitted to the GD-OTS Buyer using the GD-OTS Process Change Request (PCR) Form, QS-FM-10.7.1. The form can be obtained on the GD-OTS SharePoint collaboration site. Note: the manufacturer of a Commercial/COTS item used for Baseline Qualification is considered part of the Qualified Baseline and subject to these requirements should there be a need to change the manufacturer. Commercial/COTS items may be purchased from any distributor as long as the manufacturer is the manufacturer established as part of the Qualified Baseline. (Commercial/COTS items are as defined in FAR 2.101)

GD-OTS will determine the level of verification required for every change. Depending on the level of change, Validation Not Required, Internal Validation, First Piece Inspection (FPI), a First Article Test (FAT), a Tailored FAT, or a Requalification may be required. The Seller shall not implement such changes, or commence validation activities without prior review and approval of GD-OTS. Once the appropriate level of validation has been agreed upon, the Seller shall proceed with validation in accordance with the following requirements. Validation activities shall be performed with the facilities, production processes, methods, materials, personnel and equipment that will be used for production. Documentation associated with the approved baseline (i.e. Process Flow Map(s), Process Control Plan(s), and Critical Characteristic Control Plan) shall be updated as defined in the approved PCR, in conjunction with the validation activity.

FAT/TFAT – Seller submits Plan using the GD-OTS FAT Plan Template, QS-TP-10.7.1. Execution of the validation shall not begin until the Plan has been approved by GD-OTS. If a Plan is rejected, Seller has fifteen (15) calendar days to submit a revision. Upon approval of a Plan, Seller must give a minimum of thirty-five (35) calendar day notice of the planned execution date. Suppliers are required to comply with all aspects of the approved plan.

Unless otherwise specified in the TDP, first article 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.



Once the Plan has been executed, seller has ten (10) calendar days after completion of test to submit a validation Report using the GD-OTS FAT Report Template, QS-TP-10.7.2. Should a report be rejected by the Government, Seller has ten (10) calendar days to submit a revision. The template can be obtained on the GD-OTS SharePoint collaboration site. Production with incorporation of the change shall not begin without written authorization from GD-OTS.

FPI – Seller submits plan using the GD-OTS FPI Plan Template, QS-TP-10.7.3. Execution of the validation shall not begin until the Plan has been approved by GD-OTS. If a plan is rejected, Seller has fifteen (15) calendar days to submit a revision. Upon approval of a plan, Seller must give a minimum of thirty-five (35) calendar day notice of the planned execution date. Suppliers are required to comply with all aspects of the approved plan.

Once the plan has been executed, seller has fifteen (15) calendar days after completion of test to submit a validation report using the GD-OTS FPI Report Template, QS-TP-10.7.4. Should a report be rejected, Seller has fifteen (15) calendar days to submit a revision. The template can be obtained on the GD-OTS SharePoint collaboration site. Production with incorporation of the change shall not begin without written authorization from GD-OTS.

Internal Validation is performed at the cognizance of the Seller. Seller shall retain records of the results of the internal validation and have them available for review upon request.

Validation Not Required - Notification is not required for Attachment 0012 Ref#s 308 and 309 however, these activities shall be documented internally by the subcontractor making the change. A PCR notification and GD-OTS approval is required for Ref# 310.

Inspection/Test Equipment Validation – Inspection and Test Equipment Validation shall be completed in accordance with the requirements of Q718.

Seller shall flow the substance of this clause to its subcontractors, including this sentence, changing the relationship of the parties as appropriate to preserve the intent of the words.

**Attachment 0012
PROCESS CHANGES**

REF#	Description of Changes
100	Design Changes
101	Design changes or changes resulting in change to system MOD designation
102	Any change impacting safety or system performance requirements
103	Changes that affect items requiring outside agency involvement (i.e. Navy Weapon System Explosive Safety Review Board (WSESRB), Army Fuze Board, etc.)
104	Changes that impact either system or component level interface requirements
105	Changes resulting from unexpected events such as part obsolescence
106	Use of a lower reliability part
107	Performance data for the new or redesigned item not sufficient to demonstrate that it will perform to the same extent as the item it is replacing



200	Changes to Manufacturing Facility
201	Manufacturing plant location change for explosives or an item with a characteristic classified as Safety, Special, Critical, Major or Minor.
202	Manufacturing plant location change for an item without a characteristic classified as Safety, Special, Critical, Major or Minor.
203	Out of production over twelve months for explosives or an item with a characteristic classified as Safety, Special, Critical, Major or Minor.
204	Out of production over twelve months for an item without a characteristic classified as Safety, Special, Critical, Major or Minor.
205	Addition of a production line for explosives or an item with a characteristic classified as Safety, Special, Critical, Major or Minor.
206	Addition of a production line for an item without a characteristic classified as Safety, Special, Critical, Major or Minor.
207	Dismantling and restarting the production line for explosives or an item with a characteristic classified as Safety, Special, Critical, Major or Minor.
208	Dismantling and restarting the production line for an item without a characteristic classified as Safety, Special, Critical, Major or Minor.
209	Machine Control Upgrades for an item with a characteristic classified as Safety, Special, Critical, Major or Minor.
210	Machine Control Upgrades for an item without a characteristic classified as Safety, Special, Critical, Major or Minor.
211	Replacing an existing piece of machinery or test equipment for an item with a characteristic classified as Safety, Special, Critical, Major or Minor.
212	Replacing an existing piece of machinery or test equipment for an item without a characteristic classified as Safety, Special, Critical, Major or Minor.
213	Adding a new machine for an item with a characteristic classified as Safety, Special, Critical, Major or Minor.
214	Adding a new machine for an item without a characteristic classified as Safety, Special, Critical, Major or Minor.
215	Machine Modification for an item with a characteristic classified as Safety, Special, Critical, Major or Minor.
216	Machine Modification for an item without a characteristic classified as Safety, Special, Critical, Major or Minor.
217	Changing the sequence of the manufacturing process that affects explosives or for an item with a characteristic classified as Safety, Special, Critical, Major or Minor.
218	Changing the sequence of the manufacturing process for an item without a characteristic classified as Safety, Special, Critical, Major or Minor.
219	Moving test equipment/machines within a facility for an item with a characteristic classified as Safety, Special, Critical, Major or Minor.
220	Moving test equipment/machines within a facility for an item without a characteristic classified as Safety, Special, Critical, Major or Minor.
300	Changes to Manufacturing Processes
301	Major change in manufacturing process (i.e. Casting instead of forging or hog-out)
302	Minor change in manufacturing process (i.e. Heating/Cooling durations, new rework processes, new lubricant material, in-process dimensional range) that affects explosives or for an item with a characteristic classified as Safety, Special, Critical, Major or Minor.
303	Minor change in manufacturing process (i.e. Heating/Cooling durations, new rework processes, new lubricant material, in-process dimensional range) for an item without a characteristic classified as Safety, Special, Critical, Major or Minor.
304	Replacement or major repairs to a casting and press molds for an item with a characteristic classified as Safety, Special, Critical, Major or Minor.
305	Replacement or major repairs to a casting and press molds for an item without a characteristic classified as Safety, Special, Critical, Major or Minor.



306	Minor changes to casting and press molds to maintain parting lines and reduce flashing for an item with a characteristic classified as Safety, Special, Critical, Major or Minor.
307	Minor changes to casting and press molds to maintain parting lines and reduce flashing for an item without a characteristic classified as Safety, Special, Critical, Major or Minor.
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
310	Minor changes to work instructions that have no effect on the process (i.e. clarification)
400	Changes to Material or Supply of Material
401	Change in supplier of explosives or end item part for an item with a characteristic classified as Safety, Special, Critical, Major or Minor.
402	Change in supplier of end item part for an item without a characteristic classified as Safety, Special, Critical, Major or Minor.
403	Change in supplier of the material for an item with a characteristic classified as Safety, Special, Critical, Major or Minor.
404	Change in supplier of the material for an item without a characteristic classified as Safety, Special, Critical, Major or Minor.
405	Change in supplier for component within an end item part with a characteristic classified as Safety, Special, Critical, Major or Minor.
406	Change in supplier for component within an end item part without a characteristic classified as Safety, Special, Critical, Major or Minor.
407	Change from one qualified test laboratory to another qualified test laboratory for an item with a characteristic classified as Safety, Special, Critical, Major or Minor.
408	Change from one qualified test laboratory to another qualified test laboratory for an item without a characteristic classified as Safety, Special, Critical, Major or Minor.
500	Plating and Coating
501	New Supplier or Change in Supplier for Plating or Coating
502	Changes in the supply of chemicals used for cleaning or processing during Plating or Coating
503	Changes in cleaning, process times, temperatures, chemical concentrations, etc. used during Plating or Coating
600	Changes Not Listed within Attachment 12

Q728-1 Pre-Validation Activity (Rev 06/03/20)

This clause requires the following SDRL deliverable(s): **S728-1** - See Exhibit A for details.

GD-OTS requires that a pre-validation run be performed prior to execution of any validation activity (BQFAT per Q720/Q748, FAT, TFAT, and FPI per Q728/Q748, and ITE per Q718). A pre-validation run is performed to prepare for the actual, scheduled validation mitigating the potential risk of a failure during validation.

The pre-validation run shall fully replicate the production process that will be used and validated during the BQFAT/FAT/TFAT/FPI.

The pre-validation run will be performed on the full quantity of samples, on all characteristics, and with all associated testing and performance requirements as defined in the validation plan, unless otherwise approved by GD-OTS. GD-OTS may witness all pre-validation activities. All equipment to be used in must be identified and located where it will be used in production. In addition, all paperwork will be fully



completed (AS9102 Forms, certifications, test reports, etc.) and approved by GD-OTS. The pre-validation run activities must be completed before customer notification will be issued by GD-OTS (35 calendar day notice of the planned execution date). Parts manufactured as part of the pre-validation runs or prior to the validation testing shall not be presented for delivery/acceptance.

Q728-Alt 1 Changes to a Qualified Baseline (Process Change) **Flowdown to Subcontractors Required (Rev 06/12/20)**

Seller shall not make any changes to material (including supplier), process, inspection and test equipment, or manufacturing and inspection documentation (work instructions) without prior written authorization from their GD-OTS Buyer. Seller shall document and submit proposed changes to the GD-OTS Buyer using GD-OTS Process Change Request (PCR) Form, QS-FM-10.7.1. These levels may include: Validation Not Required, Internal Validation, First Piece Inspection (FPI), a First Article Test (FAT), a Tailored FAT, or a Requalification. Once the appropriate level of validation has been agreed upon, the Seller is responsible for conducting of the validation activity. The Seller shall not implement such changes, or commence validation activities without GD-OTS coordination and approval. Validation activities shall be performed in accordance with the approved validation plan and with the facilities, production processes, methods, materials, personnel and equipment that will be used for production.

Seller shall flow the substance of this clause to its subcontractors, including this sentence, changing the relationship of the parties as appropriate to preserve the intent of the words.