The purpose of this document is to outline the quality specific recommendations for restarting supply chain operations following a shutdown of an operation due to a pandemic. This document is intended to *supplement* any/all existing documents that reference start-up or restart processes. It provides additional specific information required for leaders across all functions to bring the end-to-end supply chain back to running at full or partial capacity.

***Quality Recommendations For A Site Start Up***

| Workstream: Aspect of Workstream | Responsible Organization | Key processes to be Addressed | Owner/Resource | Supporting Process Documentation |
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| Workforce:  Proper Training | Plant | * Identify where additional training is required, especially for employees who are working in an area they were not working in prior to the shut down * Re-affirm, through quality orientation, what quality control requirements are relevant to each employee, and confirm understanding * Re-affirm key support resources for the operators should any questions arise, specifically regarding quality or safety, during the restart time. (First 30 days) | Owner: Plant Quality Leader  Resource: | Local, Site specific quality procedure for startup  Ensure right production personnel resume to work, especially the people for critical process (COC, PTC and Special Processes) |
| Workforce:  Gauges and Other Quality Equipment | Operations, ME, Quality | * Ensure that all functional gauges are properly calibrated * Utilize the MSA procedure if new operators are being introduced to the station * Review all, applicable process documentation for adequacy | Owner: Plant Quality Leader, Operations Leader  Support: Operations leaders, managers and team leaders, line quality engineers | Local, Site specific quality procedure for start up  \*Ensure equipment, facility, fixture/gauge are in the correct status and maintain/repair/calibrate as appropriate. |
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| Workforce:  Product Traceability | Operations, ME, Quality | * Ensure that product that is being introduced into production is clearly identified by lot number, and if possible, serialized individually * Ensure that first piece production is clearly identified by month, day, time, and either lot number or specific part serial number * Ensure that the last piece produced on a given shift is confirmed to be properly inspected and that the part meets all required specification | Owner: Plant Quality Leader, Operations Leader  Support: Operations leaders, managers and team leaders, line quality engineers | Local, Site specific quality procedure for start up  \*Ensure all product traceability.  # Retain records of first off and last off daily. |
| Workforce:  Non-Standard Process | Operations, ME, Quality | * Any non-standard processes must be approved by the area, and site quality leaders * Any product produced using a non-standard process must be clearly identified, and segmented for clear visibility through the production process, until receiving approval to be placed in the normal production population | Owner: Plant Quality Leader, Operations Leader  Support: Operations leaders, managers and team leaders, line quality engineers | Local, Site specific quality procedure for start up  \*Ensure to get approval for any repair or rework. |
| Workforce  Process Control | Operations, ME, Quality | * Statistical Process Control (SPC) Procedures must be reviewed for adequacy * Strict guidelines should be followed to migrate from 100% inspection, to the prescribed sampling frequency, indicated in the local procedure * Process control should be highly monitored until control charts indicate stability | Owner: Plant Quality Leader, Operations Leader  Support: Operations leaders, managers and team leaders, line quality engineers | Local, Site specific quality procedure for start up  #Ensure key process capability to meet requirement especially on SPC control. |
| Workforce  Raw Material Introduction | Operations, ME, Quality | * Ensure that the correct material is being brought to the line for processing by checking part number, work order, and line schedule, if applicable * Ensure that material being brought to the line is marked as having been accepted by the responsible people or process | Owner: Plant Quality Leader, Operations Leader  Support: Operations leaders, managers and team leaders, line quality engineers | Local, Site specific quality procedure for start up  # Ensure to use the correct raw material or components. |
| Workforce  EOL and Functional Test | Operations, ME, Quality | * Ensure that the end-of-line test equipment has been thoroughly tested and confirmed to be capable to detect performance features that do not meet specification * Ensure that all other functional test, like leak test, have been either re-calibrated, or validated with approved boundary samples and are fit to be placed back into the process | Owner: Plant Quality Leader, Operations Leader  Support: Operations leaders, managers and team leaders, line quality engineers | Local, Site specific quality procedure for start up  # Ensure EOL test / Leakage test perform well and keep records. |
| Supply Chain:  Supplier Quality Improvement Engineer (SQIE) | Supplier Quality, Plant Quality | * Ensure that all material coming from the supply base has been validated by the appropriate SQIE, and is marked accordingly * Ensure that all applicable start up processes have been completed at the supplier, including, and up to, a PPAP * Ensure that where required, process control sustainability has been documented and confirmed by the responsible SQIE * Ensure required start up quality confirmation, as a part of increased inspection has been completed | Owner:  Supplier Quality  Support: Operations leaders, managers and team leaders, line quality engineers | Local, Site specific quality procedure for start up  # Ensure to provide SQIE break point of resume to production  #Ensure to provide SQIEs the inspection reports of first 3 batches since resume to production with quality leader signature. |
| Supply Chain:  Supplier Quality Improvement Engineer (SQIE) – Supplier Site Activities | Supplier Quality, Plant Quality | * Ensure that safe launch, or a comparable process has been completed at the supplier’s site * Ensure that similar disciplines are being followed at the supplier’s tier 1 suppliers * Ensure that suppliers are aggressively pursuing all actions that could contribute to a Zero-Defect Mentality (ZDM) and are keenly aware of the necessity of a smooth start up for us and our Customers | Owner:  Supplier Quality  Support: Operations leaders, managers and team leaders, line quality engineers | Local, Site specific quality procedure for start up  #SQIE will evaluate any risk of supplier resume to production and kick off safe launch on applicable suppliers.  # Ensure your sub-supplier follow the same actions that you are requested to follow.  #Supplier takes other actions to ensure quality as needed per your respectively situations. |