Global Supplier Quality Manual

MACHINED Quality™

Document Version: SQ001

DME
Global Supplier Quality Manual

INTRODUCTION

At DME, we believe that continually improving our equipment, products and processes is key to increasing our competitive market position worldwide and ensuring our continued success. To meet our customers' world-class expectations, a total commitment to customer satisfaction and continuous quality improvement must be shared by DME and all of its suppliers. As a part of the supply chain, together we must maintain effective criteria to help assure conformance to specifications, adequate control of manufacturing processes and continuous improvement of those processes.

As we strive to become better at everything we do, we set higher standards for our equipment, products and ourselves. We must also expect more today from our suppliers, in terms of quality and commitment, and these changes will result in greater customer satisfaction and more efficient use of resources.

PURPOSE

The purpose of this manual is to communicate DME Supplier Quality requirements and expectations to suppliers. It is the intent of DME to do business with suppliers who are able to provide parts, materials, processes and services consistently to specifications, at a competitive price, and in accordance with the defined delivery schedule. The manual is intended to assist suppliers in their understanding of requirements regarding specific supplier quality management, communication, and reporting processes.

SCOPE

The requirements of this Manual apply to all suppliers of finished goods, production materials (raw or parts), as well as outside processes and services where applicable. This Manual is the quality standard for every DME supplier worldwide. This common global Manual allows DME to evaluate all suppliers across all product groups around the world based on common expectations and performance standards. This information applies to all suppliers who have interest in doing business with DME. Any questions regarding the applicability of the requirements contained in this manual should be directed to your DME contact(s) for resolution.

This Manual supersedes all other prior versions and this version is the only officially recognized release of this document.

RESPONSIBILITY

It is the responsibility of the supplier to review, understand, and satisfy the requirements of this manual and any other applicable requirements as part of the acceptance of purchase orders from DME. The supplier should obtain any referenced documents to ensure full compliance with all applicable requirements.

DME will maintain and document changes in the general supplier quality requirements included in this manual. Revisions to the DME Supplier Quality Manual will be available on line or can be obtained through DME's Procurement department.

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1.0 GENERAL SUPPLIER QUALITY SPECIFIC REQUIREMENTS

1.1 Quality System

The DME's requirement standard for our supply base is registration to the latest edition of ISO 9001. Exceptions to the DME standard will be evaluated on their individual merit. In addition, the supplier must also adhere to all other requirements of this manual. Reference Appendix 1

1.2 Quality Planning

"Defect prevention is preferred to defect detection." Quality Planning is a systematic process for establishing measurable objectives and requirements, and lays down a sequence of steps for realizing them within a specified timeframe.
Suppliers are required to document a plan for quality that addresses the following:

- Verification of DME requirements
- Having the necessary resources to provide desired parts (people, equipment, time, finances)
- Processing and specification verification procedures
- Delivering the product or service according to established requirements and timing

1.3 Engineering Prints and Specifications

Suppliers are required to ensure they have received and fully understand the requirements of all Engineering Prints and Specifications related to the product(s) that they furnish DME.

- Any missing and/or questions related to the understanding of the intent of DME Engineering Prints and Specifications shall be communicated to Procurement prior to initiating supply to DME.
- Any revisions to the Engineering Prints and Specifications will be communicated through the DME procurement, or through revision levels called out on Purchase Orders.

1.4 Drawing and Change Control

Suppliers must have documented systems in place to control changes to prints, specifications, processes, or produced parts. Systems should be capable of handling changes being requested by the customer, and also changes requested by the supplier.
The supplier's quality system pertaining to Prints and Specifications must contain:

- Documented procedure that describes the method used for the receipt, review, distribution, and implementation of all changes to drawings and specifications.
- Control of obsolete drawings and specifications.
- Method used to contain new or modified parts until approved by the customer.

1.5 Supplier Material Compliance

DME requires suppliers to understand and verify the composition of their raw materials. At any time DME reserves the right to request raw material confirmation on any supplier purchased product.

- Supplier should be able to provide a Certificate of Analysis (CoA) report when required.
- A material composition report may be required to verify that the raw material contained within the purchased product meets known or specific industry standards.

- DME can require ongoing material certification be provided on a routine basis for any purchased product at the supplier's expense during the life of the product.

1.6 Control of Subcontracted Materials/Parts/Services at Sub-Suppliers

The Primary Supplier is responsible for the quality of parts, materials and outside processing provided by their sub-suppliers and sub-contractors. The extent of the controls may vary, depending on the nature and complexity of the product and processes, but should normally include:

- Evaluation and qualification of sub-supplier facilities
- Control to ensure that raw materials used meet DME's requirements
- Controls to ensure that the sub-suppliers of parts used are those approved by DME, where applicable.
- Part qualification, including first article inspection
- Control of drawings/revisions
- Control of nonconforming material
- Corrective action and preventive action programs
- A continuous quality improvement program

Where appropriate, DME may specify the sub-suppliers that may be used, however, it does not absolve the Primary Supplier of the ultimate responsibility for the quality performance of their sub-suppliers.

1.7 Control of DME Supplied (consigned) Materials/Parts

Whenever DME supplies (consigns) materials/parts to a supplier, the supplier is responsible for properly verifying, storing and maintaining those materials/parts. DME can request inventory verification at any time and the supplier will be responsible to provide per the request. Any materials/parts that are lost, damaged or deemed unsuitable must be reported to DME immediately for disposition.

2.0 SUPPLIER QUALIFICATION/ASSESSMENT PROCESS

All suppliers of production materials to DME must be qualified suppliers. The objective of DME's Supplier Qualification/Assessment Process is to identify potential suppliers who have operational systems and controls which are compatible and complimentary to DME and to periodically evaluate current suppliers to ensure those systems and controls are being sustained.

The extent of the qualification process is dependent upon the criticality of product purchased, services provided and other factors determined by DME. The qualification process consists of four parts:

- Supplier RFI (Request for Information)
- New Supplier Self-Assessment - A quality management system self-assessment completed by the supplier, using the DME supplier assessment survey form On-site Assessment (OSA) tool.
- On-site assessment – Audit conducted at the manufacturing location, if determined, by DME personnel or their authorized agents. (OSA tool)
- Periodic Reevaluation of Existing Suppliers – re-assessment of the supplier to determine status in DME supply base.

Reference Appendix 2 & 12 Regional Addendums

3.0 PART QUALIFICATION

For conditions requiring parts, materials, processes and services qualification, the Suppliers will submit all qualification data in accordance to DME's First Article – Supplier Part Approval Process (FA-SPAP). First Articles– Supplier Part Approval Process is required, but not limited to the following:

- New part being ordered for the first time
- Existing part ordered from new source.
- Existing part from same supplier at a new location.
- Design change to the current part (only inspection for the change is required)
- Part that is purchased for Engineering which will be used for production in the future
- Part from new tool which has been ordered to replace a worn tool
- Verification of tool repair

A FA-SPAP requirements checklist will be provided to the supplier detailing the supportive documentation to be submitted for approval consideration.
The content of the FA-SPAP submittal package consists of the following:

- First Article – Supplier Part Approval Process Requirements Checklist
- Part Submission Warrant (PSW)
- Submission Samples – Visual Inspection of Workmanship
- Dimensional Inspection Report and Numbered Print
- Material Certification and Test Report
- Process Flow Diagram and Process Visualization
- Packaging Proposal/Plan
- Performance and Durability Test Data
- Part Specific Requirements

In some cases DME personnel may wish to be present during the production run of parts to be submitted for the FA-SPAP. This will allow DME to validate and verify the process before any product is shipped.

Where possible, all documents should be submitted to the Procurement and Quality representatives in electronic format (preferably Adobe Acrobat or Microsoft Office).

Reference Appendix 3, 4, 5, 6

4.0 SUPPLIER CHANGE MANAGEMENT

All product design, process, source, location and material changes and/or deviation requests to the current Part approved level are required to be submitted for formal approval through a Supplier Process Deviation and Change Request (SDCR) , this includes any and all sub-tier supplier changes and/or deviations. This requirement also applies to any change resulting from any form of process or product improvement activity or any previous product nonconformance. Suppliers must obtain written approval from DME prior to implementation of any requested change or shipment of any product containing deviation to DME specifications.

A (SDCR) Form is used to request a temporary deviation or permanent change to a released part, process, drawing, specification or material. The supplier will complete the form for either a deviation or change request and submit it to Procurement and await approval prior to taking action.

Reference Appendix 7, 8

- A new Deviation form has to submitted for EACH shipment containing deviated parts
- The Change Request approval process is directed at a specific part number for a specified revision level produced in a specific area of the manufacturer's facility. **Suppliers may not make any changes in their process, location, material, or to the part without written SDCR approval from DME.**
- Suppliers will be responsible for the costs of any testing required by DME or DME's end customer to validate the change/deviation, requested by a supplier, will not negatively impact the performance of the DME or DME's end customer's product and will be communicated to the supplier by their Procurement Representative.

5.0 PACKAGING PLAN & CORROSION PREVENTION

Each supplier must adequately plan for packaging and corrosion prevention. Suppliers will provide packaging that provides protection from any damage that may occur in transit. The Packaging Proposal/Plan Form needs to be completed and submitted as part of the FA-SPAP documentation for part qualification.

6.0 CORRECTIVE AND PREVENTATIVE ACTION REQUIREMENTS

DME issues a Supplier Corrective Action Report (SCAR) to a supplier when non-conforming parts or material are found at incoming inspection, in assembly, in test, or by a DME customer. They can also be issued as a result of a supplier audit.

6.1.1 Non-Conformance Determination

Non conformity is defined as the non-conformance of Production approved parts to one or more of the following documented requirements:

- Print dimensions.
- Material Specifications.
- Engineering Specifications.
- Packaging Specifications.
- Mixed/wrong parts within a shipment.
- Improper identification of parts.
- Failure of a part to perform during the warranty period DME has extended to their end customers due to a supplier created discrepancy.

6.1.2 Supplier Notification of a Non-Conformance

When a supplier non-conformance has been identified a Supplier Corrective Action Request (SCAR) notification will be sent to the supplier with the expectation of them starting a Corrective Action Response using a formal problem resolution methodology. Supplier will undertake to receive and respond to the SCAR form which is the official communication tool for reporting and resolving problems.

A sample of the SCAR Form with Expectations and Deliverables can be found in Appendix 9, 10

6.1.3 Supplier Initial response to a SCAR

Suppliers are required to update the SCAR and provide an initial response within 48 hours (two working days) of notification date. If the suppliers fails to respond to DME within expected time frame, the supplier will be deemed to have accepted the warranty claim and warranty recovery obligations will be the sole responsibility of the supplier.

- The supplier's Initial response is an acknowledgement that the Supplier has been informed of the problem, and is taking appropriate actions.
- The initial response must define their problem statement utilizing the customers information, supplier part and process knowledge.
- If a containment plan is applicable, it must clearly define the containment actions at the supplier's facility to assure that no nonconforming product is shipped to DME. If suspect product has already been shipped, the supplier must address all suspect stock in transit and any stock at DME. The supplier will assist DME in identifying customer risk by identifying all suspect lot numbers and associated quantities involved.

6.1.4 Root Cause(s) and Solution Identification

It is the supplier's responsibility to confirm the root cause(s) of the discrepancy identified and identify effective solutions to eliminate the true root cause(s). A written preliminary corrective action must be sent to DME within ten (10) working days identifying the root cause(s). The supplier must report the results of the Supplier's investigation into the root cause(s) of the problem. There are many potential tools to assist the supplier with this including (but not limited to); brainstorming, 5 why analysis, capability (quality) index, control chart, decision matrix, design error-proofing / process mistake-proofing, design of experiments, histogram, hypothesis testing, linear regression analysis, run and trend charts and design / process failure mode effects analysis.

Although DME does not prescribe a specific root cause analysis method, the supplier shall demonstrate root cause validation on their SCAR response. DME representatives shall be permitted to review the submitted root cause validation. Where, in DME's opinion, the measurement and analysis plan does not clearly validate the potential root cause(s), DME may reject the suppliers response to the SCAR.

Where root cause(s) have been effectively validated, as determined by DME and /or the end customer, the supplier is responsible for proposing a plan to implement permanent solutions and verify their effectiveness. Where proposed changes impact the design or approved processing of a product a Supplier Deviation and Change Request shall be generated, referencing the SCAR.
If your proposed plan is rejected, your organization is responsible for providing alternative plans to provide conforming material.

6.1.5 Permanent Solution Implementation

Once approved, the supplier is responsible for implementing the proposal. The SCAR shall be updated by the supplier to indicate progress. DME will monitor the progress based on milestones and effectivity dates of the planned activities. Where assistance is required to achieve the plan, the plan cannot be implemented as defined or will not solve the original problem, the supplier shall notify DME before due dates are compromised.

6.1.6 Permanent Solution Effectiveness and System Changes

The supplier is responsible for providing evidence of the effectiveness of the corrective action to prevent or control the root cause(s) on the non-conformity. This evidence shall be included in the SCAR response. Where the evidence provided does not clearly indicate the problem has been solved, the supplier will be notified to include additional or more comprehensive evidence.

6.1.7 Final resolution of the Non-conformance

Final resolution of the corrective action will be made within thirty (30) working days of the supplier's submittal. Any request for additional time should be directed to DME and shall be in writing. An extension of time may be granted based upon the corrective actions required or the nature of the

nonconformance, however; a detailed timing plan will be provided by the supplier targeting implementation and resolution of the correction and preventative action(s).

6.2 Responsibility Assignment for Corrective Actions

- Responsibility of Supplier

  Part or material analysis results and actions shall be documented using the SCR format. This format is also utilized to monitor the effectiveness of corrective actions over time by each component. The Supplier has the obligation and responsible for any reasonable and customary costs associated with the non-conforming part or material.

- No Fault Found (NFF)

  Part or material analysis results in a declaration of NFF after completing the Corrective Action Process. Supplier must clearly describe, document and provided result data on how they arrived at this conclusion. The NFF status in the warranty analysis process must follow systematic elimination of potential root cause factors. NFF typically describes a scenario whereby testing indicates the returned part meets DME and/or our customer part and performance requirements as defined in purchase orders, Purchase specifications and warranty terms and agreements. DME must disposition.

- Responsibility Not Supplier

  When the supplier investigation has determined the defect is not their responsibility, with the potential of Service or Customer misuse, the supplier needs to provide all supporting documentation for justification of this type of failure.

In the event that DME disagrees with a supplier response, DME will give timely notice of its objection. Should DME decline a submitted response, the supplier will be asked to amend it. A rejected supplier response, where the parties do not agree as to content effectiveness, shall not be binding upon DME. The supplier shall retain the affected parts until the issue is resolved in a positive and professional manner; such that DME customers will concur with our suppliers root cause and corrective action analysis, including supporting documentation.

6.3 Supplier Liability, Chargeback Process and Cost Recovery (COST OF QUALITY)

In the event that non-conforming parts or material result in a cost liability to DME, DME reserves the right to charge the supplier costs associated with the resolution of the non-conformance. It shall be the supplier's responsibility to aid DME in evaluating and correcting the problem. If necessary, DME will request the Supplier to be on-site to help support nonconforming activities and present corrective actions to the DME Management team. The Supplier has the obligation and responsible for any reasonable and customary costs associated with the non-conforming part or material including but not limited to:

- First Article rejection
- Sorting of suspect material
- Third party containment
- Premium Freight / Shipping
- Warehousing
- Rework/Repair
- Production Downtime
- Overtime
- Scrap
- Administrative
- Engineering effort
- Laboratory testing
- Customer Charges
- Warranty / Recall
- Travel and associated costs

Costs incurred may be reviewed with Procurement and or assigned point of use representative and may be debited from the suppliers account at DME discretion. The cost to process an SCAR is $250 USD and that will be the minimum charge that may be passed on to the supplier for each occurrence. A supplier shall comply with DME's process to recover costs associated with a supplier's performance liability. Upon notification of the intent to debit, if there is no response from the supplier, DME will consider this lack of response as acceptance of the charges.

7.0 SUPPLIER MONITORING

DME monitors its suppliers to ensure they continue to meet DME's requirements, and to ensure that the supplier continues to ship acceptable parts. Monitoring methods may consist of:

- Supplier Scorecard & Performance Evaluations
- A quality management system surveillance audit at the supplier's facility
- An on-site audit of the supplier's control plan
- A random incoming inspection audit of a batch of product
- Source inspection of product at the supplier's facility
- Nth Article Inspection
- Review of supplier-furnished data packages
- A supplier progress review meeting conducted periodically at the supplier's site or DME to review supplier performance and progress

Reference Appendix 11

8.0 SUPPLIER IMPROVEMENT INITIATIVES

8.1 Continuous Improvement

The supplier should promote and implement a continuous improvement philosophy applying proven methodology and processes. These methods and processes shall be used throughout the Supplier organization to continually improve the quality, delivery, cost and service of supplier products. Recommended tools of the continuous improvement process are:

- Benchmarking
- Brainstorming
- Pareto Analysis
- 5-Why Analysis
- Decision Tree
- Cost Benefit Analysis
- Cause and Effect
- Process Capability/Performance
- Process Mapping, etc.
- Mistake Proofing

DME Suppliers are expected to create and maintain continuous improvement plans focused on bettering Quality, Delivery, Cost, and Service performance. Regular reviews will be scheduled to address progress and results of improvement plans. Supplier continuous improvement activity is taken into account in scorecard performance and in supply strategy, and is indicated by the Segmentation Level. The segmentation level is a value (1-4) based on the monthly and year to date values on the Scorecard. DME's desire is to partner with suppliers that meet the criteria of a Level 1 or 2 performers. Any supplier that consistently performs at the Level.

SEGMENTATION				
PERFORMANCE LEVEL	ADDITIONAL CRITERIA	SUPPLIER SEGMENTATION	SUPPLIER BENEFITS	ACTION FOR CATEGORY TEAM
Level 1	Commodity Specific Technology, Process Capabilities, Consignment, etc.	Strategic	Recommend for new Business	Involve in New Part Development efforts, other Supplier integration efforts
Level 2		Preferred	Potential for additional business	Work to raise to Level 1 Performance
Level 3		Maintain	No additional new business	Work to raise to Level 2 or 1 Performance
Level 4		Non-Performing	None	Consecutive months of Level 4 - Implement improvement plan or present detailed plan to qualify alternate source

The supplier's management should take a lead role in continuous improvement by embracing the concept and by adopting continuous improvement as a key element of their business plan.

8.2 Supplier Development

Supplier development activities within the supply base allow DME and our suppliers to drive continuous improvement efforts. Supplier development initiatives within a supplier should focus on the following:

Improving process control:

- Improving quality systems
- Improving product quality
- Improving supplier delivery
- Reducing costs
- Improving Supply Chain effectiveness
- Reducing lead time
- Improving productivity
- Increasing capacity and Training

DME will select key suppliers for development who present the best opportunity for improvement and who present the greatest potential impact to the organization. Once a supplier has been selected, a cross-functional team consisting of appropriate DME and supplier personnel will be formed to work together and have regular follow-up meeting to ensure that certain targets are achieved. DME many choose to provide training to suppliers on techniques for operational and process improvement.

8.2.1 Soft Supplier Development (SSD)

In case the supplier resulted to level of Conditional Pass there is no barrier to start our collaboration but only in case if the supplier commits he is willing to be developed according DME needs. This kind of Supplier Development can be called "SOFT SUPPLIER DEVELOPMENT (SSD)" due to the supplier takes care of the majority of the development works by himself and RQM is involved just to provide development direction.

This kind of development is mainly managed using phone calls, e-mails, on-site reviews at supplier premise to see whether actions performed in real and all is covered using Action Plan tool (stored in FA-SPAP workbook).

Based on development result RQM decides whether the supplier has to be re-audited or whether the development might be closed based data provided against all the actions.
In case the supplier does not support this development, RQM escalates this to Supply Chain Manager (SCM) and this team of RQM and SCM makes mutual agreement how to progress with particular supplier (Strategic Negotiation, Resourcing, Do Not Source List etc.). This SOFT SUPPLIER DEVELOPMENT should be targeted to not exceed 6 months from On-Site Assessment (OSA) result announcement.

8.2.2 Hard Supplier Development (HSD)

In case the supplier did not pass the on-site assessment RQM asks the supplier to commit whether he is willing to be developed. RQM also verifies with Supply Chain Manager whether such supplier development will be found as cost effective. In case the supplier commits he would like to be developed and SCM agrees on such development RQM starts to plan so called "HARD SUPPLIER DEVELOPMENT (HSD)".
This level of supplier development utilizes a determined frequency of supplier visits to review progress. Regular reviews at supplier site have to be planned in advance and RQM is responsible to define this frequency. Hard Supplier Development Review has a target to be performed at least once a month. Whole development should be targeted to have by bi-weekly calls with supplier and will utilize the DME ACTION PLAN or similar tool. Supplier will have a re-assessment targeted within 1 year from the initial Hard Development.
Further progress is depending on assessment result. If the supplier falls back to category REJECTED/ Hard Development Needed, the procurement team must resource such supplier in shortest possible time.
RQM has a right to stop Hard Development activities in case the supplier does not collaborate to the development established criteria.

8.2.3 Supplier Development Based on Performance result

RQM performs regular reviews with local quality team. Frequency of those reviews should be the best bi- weekly but at least once a month.
Quality Engineering is responsible for supplier complaints/ Supplier Quality utilizes data and prepares for such reviews. PARETO analysis to be used to determine 80% of pain in supply chain.
He follows SOFT SUPPLIER DEVELOPMENT method and tools.
In case the supplier reaches Yellow (Y) or Red (R) result the SCM and RQM defines further strategy how to develop or resource such partner.

Reference Appendix 12 Regional Addendums

8.3 FOCUS SUPPLIER PROGRAM – QUALITY MEETINGS

Suppliers with less than the expected Quality Levels of 100% may be required to participate in a Focus Supplier Program (FSP) Quality Meetings when their performance drops below expected levels. Meetings will be facilitated by DME. These FSP Quality meetings and the need and/or frequency will be at the discretion of DME.

The purpose of the FSP meetings is for Suppliers to present containment and corrective actions to improve their performance in the deficient areas identified by DME. Suppliers can be called to participate in a FSP meetings for:

- Poor Quality
- Repetitive Issues
- Responsiveness to concerns raised by DME
- Delivery discrepancies, against planned delivery schedules.

8.4 Supplier Quality Improvement Plan (QIP)

A supplier whose performance falls below 70% for two consecutive months will, at the DME's discretion, be put on a Supplier Quality Improvement Plan. This will be implemented by either the Supplier Quality Manager or the Regional Quality Manager. The activity will be reviewed initially 2 x per month. If little or no progress is made, the supplier meetings will increase in frequency. If the supplier does not improve their score within a quarter, the supplier will be put on bid suspension and actions may be taken to start re-sourcing the business.

9.0 REGIONAL SPECIFIC ADDENDUMS

In addition to the requirements outlined in the previous sections of the Global Supplier Quality Manual, each Region (North America, Europe, Asia, India, etc.) may have additional or specific requirements. These are in addition to the requirements listed above, not in lieu of. When supplying DME facilities in multiple regions, the shipment and expectations are governed by the Global Supplier Quality Manual and the applicable addendum for that region. Reference Appendix 12

APPENDIX SECTION

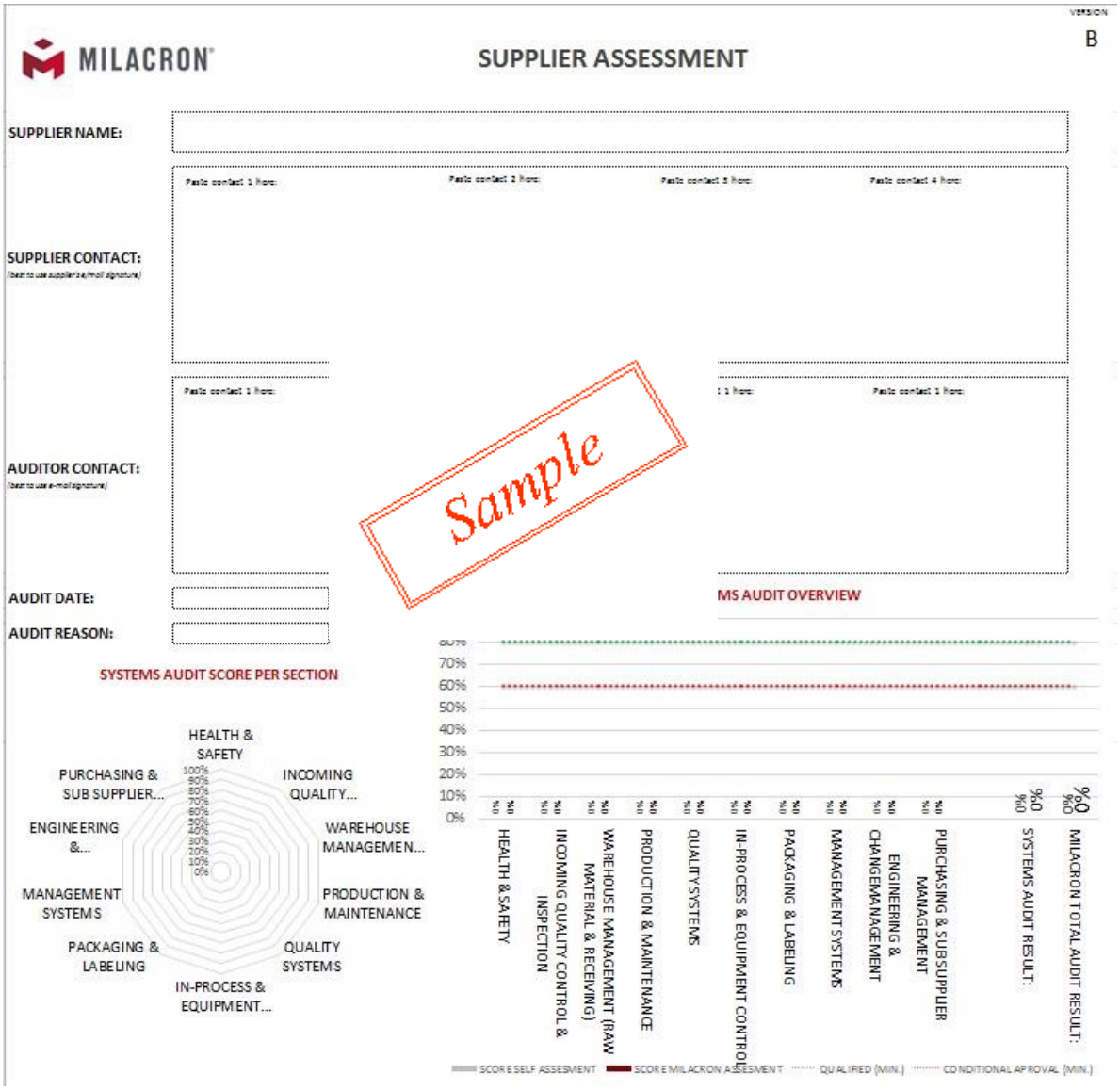
Appendix 1 - Quality System General Requirements

DME suppliers are requested to develop their Quality Systems using ISO9001 specifications as a reference. The following items are required content addressed within a suppliers Quality System

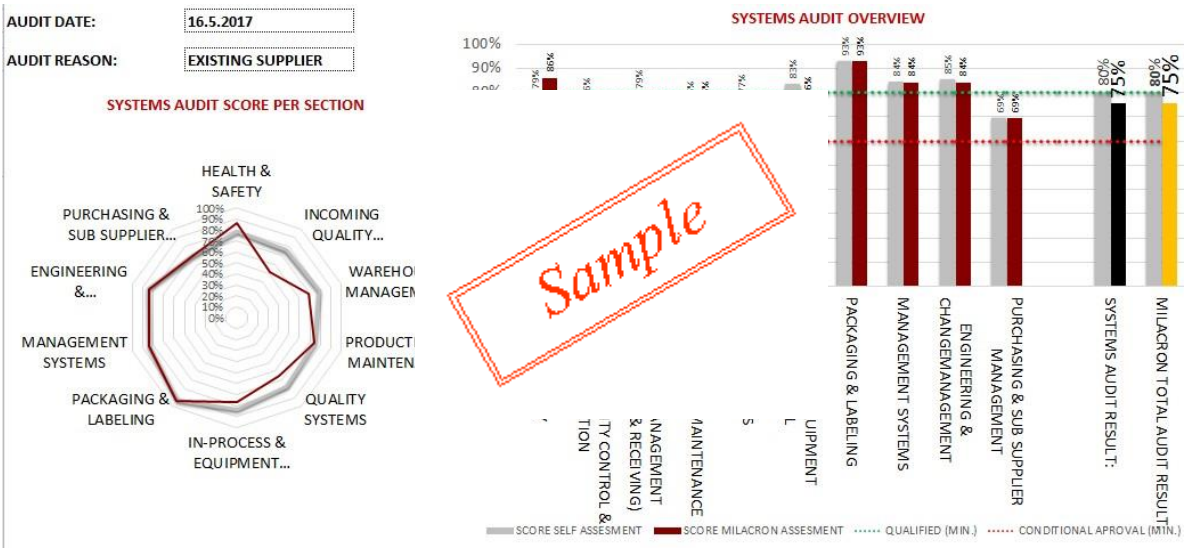
- Establishing and implementing a documented quality management system (QMS)
- Documents that are appropriate, relevant, simple, understandable and consistent with processes in use.
- Maintaining a documented QMS
- Continually improving the effectiveness of the QMS
- Determining processes, process sequence and interaction that are visible, traceable, consistent, repeatable, measurable and documentable.
- Availability of resources necessary to support the operation and control processes
- Availability of information necessary to support the operation and control of processes
- Monitoring, Measurement and analysis of processes
- Continual process improvement
- Process management
- Management and monitoring of Outsourced processes

Appendix 2 – Supplier Assessment

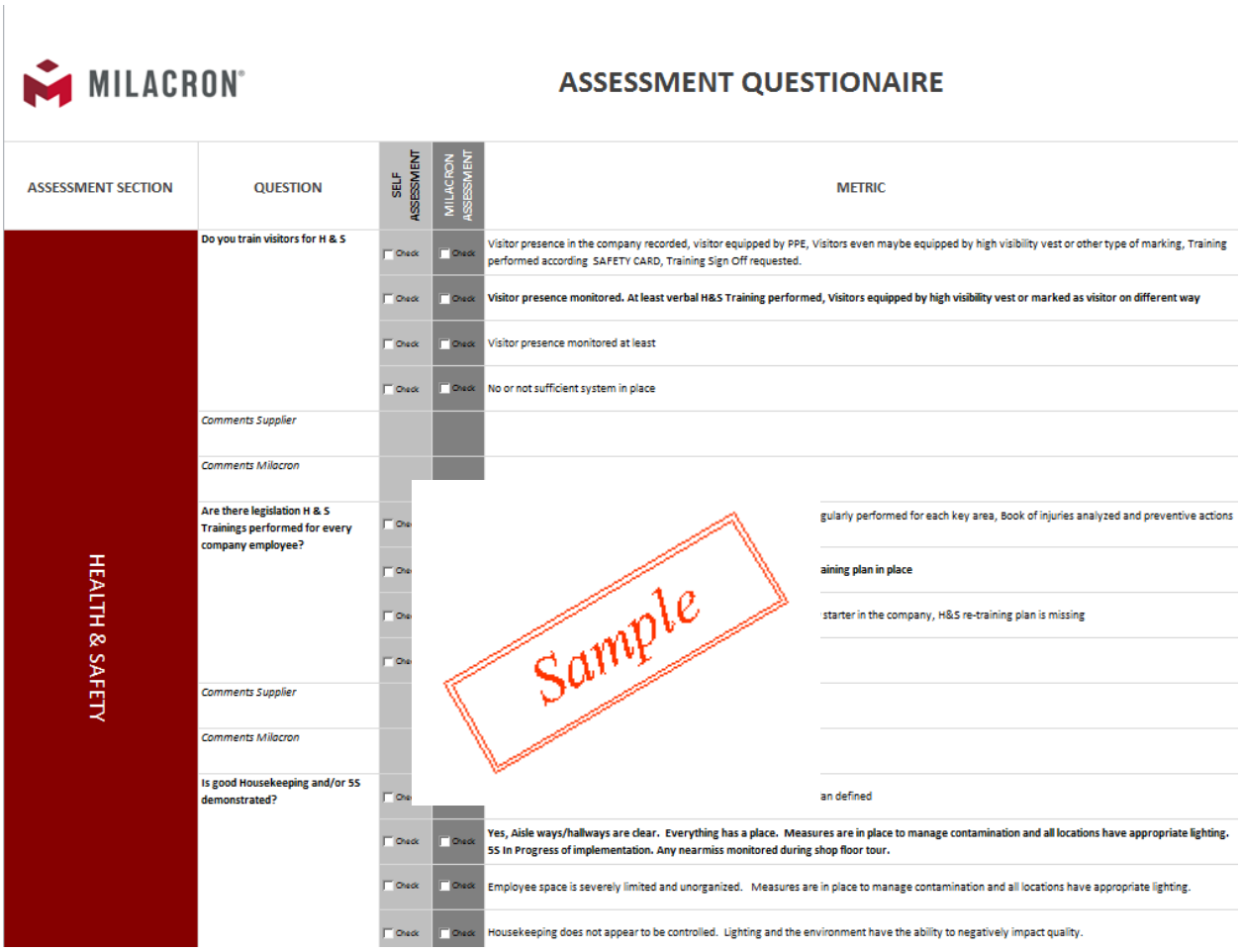
Supplier ON-SITE ASSESSMENT form
Its header level gets completed by supplier during Self- Assessment.



Example of completed questionnaire.



Assessment area of the questionnaire. Light Grey completes supplier dark grey DME RQM then. There is also space for both party comments to each question if metric does not suit particular case.



Once OSA completed the RQM has to create NC List and provide it to supplier to develop Continual Development Plan using DME CONTINUAL DEVELOPMENT ACTION PLAN.

MILACRON

LIST OF ASSESSMENT NON-CONFORMITIES

SUPPLIER: SUPPLIER A

Date: 16.5.2017

NON-CONFORMITY NO.	AUDIT SECTION	NON-CONFORMITIES FOUND DURING ASSESSMENT	NC CRITICALITY
1	INCOMING INSPECTION	Absence of good guide/ checklist how to perform inspection always the same way with maximum possible detection (LESSONS LEARNED USING FAILURE CATALOG), Absence of good definition for VISUAL ASPECTS	MAJOR
2	INCOMING INSPECTION	Missing NC material blocking tools (RED CARDS, CONES, RED TAPE) to drive immediate NC product visual segregation	MAJOR
3	CONTINUAL DEVELOPMENT	Missing **good and detailed ACTION PLAN** to drive whole company continual development (in all areas) using SMART task method	MAJOR
4	CONTINUAL DEVELOPMENT	Absence of detailed INTERNAL FAILURE h automatic reporting	MAJOR
5	WAREHOUS	To protect parts waiting essing with plastic foil	MINOR
6	WAREHOUS	storage (Dangerous, ner)	MINOR
7	OUTGOING	1 of this list but for OQC.	MAJOR
8	QUALITY SY	ment of handling of NC d enough. Make sure tools nply available in all areas nt be discovered.	MAJOR
9	QUALITY SY	d LESSONS LEARNED data FAILURE CATALOG in all areas where applicable. INTERNAL, SUPPLIER, CUSTOMER issues.	MAJOR
10	IN-PROCESS CONTROL	Absence of CRIMP QUALITY MEASURES (CRIMP HEIGHT, PULL OFF TESTING or CRIMP CUT)	MAJOR
11	QUALITY CONTROL	ABSENCE OF PROCESS HEALTH CHECKS to make sure whatever process get tired over time. Example (paperwork completation, placing parts to right zone, storing properly, covering to avoid dust pollution + more)	MINOR

Appendix 3 - First Article - Supplier Part Approval Process (FA-SPAP) Requirements

1) First Article – Supplier Part Approval Process (FA-SPAP) Requirements & Checklist

First Article Inspection is performed by the Supplier in accordance with the DME drawing specified on the Purchase Order. When applicable, DME sends the supplier a First Article Requirements Checklist, listing the steps and information that must be submitted for qualification of the component or assembly for production. The checklist items selected are based on the type of part or assembly to be supplied.

DME reviews Supplier FA-SPAP package for completeness, accuracy and legibility, verifies randomly selected characteristics and features for accuracy, compliance and documents the function trial of the part, as required. If DME accepts a FA-SPAP using the supplier supplied data and if found out later that the parts do not meet the DME specification, our acceptance of the FA-SPAP does not alleviate the supplier from future responsibility. Conforming FA-SPAP Reports are approved and distributed. Nonconforming FA-SPAP Reports are returned back to the Supplier so that corrections can be made. Continuous rejections for a FA-SPAP submittals may prompt the Supplier to be restricted from consideration of current and future business.

2) Part Submission Warrant (PSW)

The Part Submission Warrant (PSW) shall be completed and sent in to DME with all required documentation and sample parts. The purpose of the PSW is to document the submission and the approval of rejection of the purchased parts prior to production. DME has developed its own Submission Warrant document and this form is a required element of the FA-SPAP and must be submitted as part of the FA-SPAP. It must be filled out and signed by the supplier. The part number must match the Purchase Order or material agreement that is provided by DME. It is critical to make sure the PSW is filled out correctly, and contains accurate and legible information. A sample of the PSW described above can be found in Appendix 4

3) Submission Samples – Visual Inspection of Workmanship

DME and the supplier will agree on the number of the samples to be checked and submitted with the first article data. All samples submitted for FA-SPAP approval must be visually inspected to ensure that they are free of flaws, defects or discontinuities that might adversely affect the form, fit, function or durability of the part or that might injure a person handling the material. Such flaws may include burrs, nicks, chatter marks, scratches or contamination. A FA-SPAP may be rejected for substandard workmanship, even if such characteristics are not specifically identified on the engineering drawing or related specifications.

4) Dimensional Inspection Report & Numbered Print

DME notifies the supplier of the quantity of parts to be inspected. Parts inspected for the dimensional inspection report are randomly selected from a production run of parts, when applicable due to order or production quantity. The parts must be produced under production conditions, including material, machines, tooling, processing parameters, cycle times, etc. Any exceptions to the production conditions must be approved in writing by DME, and included in the data package submitted to DME. The supplier inspects or tests each sample for all dimensions, drawing notes, and specification requirements listed on the current revision of the DME drawing and/or specification. The supplier records the results on the dimensional inspection reports or equivalent form. The supplier also numbers a copy of DME's engineering drawing with numbered "balloons" that point to individual dimensions, characteristics and/or specifications that corresponds with the supplier's results on the Dimensional Data sheet. A copy of this numbered & ballooned drawing must be submitted as part of FA-SPAP for every submission requiring dimensional results.

Items to be "Ballooned" may include:

- Dimensions and tolerances of parts
- Visual features (Color, texture, etc.)
- Physical and mechanical properties (tensile strength, plating thickness, heat-treat hardness, surface finishes, etc.)

- Electrical requirements (performance data, functional tests, etc.)
- Any other specified requirement that you have the capability to measure or that is described in the print notes or referenced specifications

A common method of marking drawings is to use a template to draw a circle near each dimension and then to number the circles. The numbers in the circles align to the "Item Number" row of the Dimensional Inspection data form. The drawing identifications are often done in a color other than black or blue to make them more easily distinguishable from the drawing features and dimensions. The characteristic criteria identified on the print is then verified by validation data for each line item number and recorded on the Dimensional Inspection data form.

In order to make references easier, please do the following:

- When it may be unclear which characteristic a numbered circle refers to, use an arrow to point from the circle to the characteristic
- When numbering a drawing, number all of the characteristics in a particular view before proceeding with the next view
- When numbering a particular view, proceed in a single direction (e.g., clockwise, top to bottom, etc.)
- Number adjacent views consecutively: Don't skip around the drawing
- For drawings with more than one sheet, number all characteristics on one sheet of the drawing before proceeding with the next sheet. Also, always number the sheets in consecutive order starting with the first sheet
- If a drawing has charted or optional views number only those views that apply to the part as manufactured.

It is usually best to avoid such methods as:

- Numbering the characteristics in the order that they were inspected for the FA-SPAP
  Numbering by view letter (since views are typically scattered).
- When dimensions are specified at multiple locations on the drawing, the data for each location should be numbered separately.

Recording Guidelines for Data Results as follows:

- actual measurements/results for variables data (must indicate pass or fail on the inspection report)
- pass/fail for attributes data
- certifications where applicable

A simple statement that the part meets the requirements is not acceptable. For any requirements that the supplier does not have the equipment to inspect or test, the supplier may obtain reports from their sub-supplier or other test agency.

(Note: see Appendix 4 for ballooned print example)

5) Material Certification and Test Report

When requested, the supplier must provide a material certification and test report. This report must include the specification number, specified material and/or physical requirements, and the inspection/test results. A simple statement that the material meets the requirements is not acceptable. Each report must be traceable to the supplier's material, and must be signed by the organization that performed the testing.

Material data should be included on a format that allows for clear interpretation of the results. For example, material results can be addressed using a material composition report or a certificate of analysis. Either an in- house format or industry standard formats for material and performance are acceptable.

6) Process Flow Diagram and Process Visualization

A process flow chart is a quality-planning tool that helps to visualize the process. The purpose of the diagram is to document and clarify all the steps required in the manufacturing or processing of a part. The process flow chart identifies each step of the process from receipt of raw materials through shipping of parts. It also includes reaction loops/branches for out-of-control, scrap and rework situations and identifies all inspection, test and verification points. The process Flow chart can be provided in any format used within an organization. In addition to the diagram, it is recommended to include pictures of the process to provide a clearer visual understanding.

7) Packaging Proposal/Plan

The supplier must adequately plan for packaging of material shipped to DME that provides protection from any damage that may occur. The supplier will provide a documented packaging plan including container size, number of parts per container, packaging configuration, etc. Packaging will be designed to provide protection from any damage that may occur. Packaging, labeling, and shipping materials must comply with the requirements of common carriers to secure the least transportation costs. The Packaging Plan will be submitted prior to the first production shipment.

- **Packaging**

  Each supplier shall provide packaging that promotes safety, guarantees part quality, maximizes both transportation and reduces waste at a minimal cost. Packaging must ensure the conformity of the product through delivery to the intended DME facilities. The packaging plan will be submitted to the DME Purchasing Representative during FA-SPAP submission and prior to the first shipment. The packaging must be designed and developed taking into consideration the actual transportation and material handling methods. Some characteristic to be considered are functional design, right sized packaging, impact resistant fillers, individual piece wrapping, parts segregation and other protective measures. Separate protective packaging for each part with cosmetic requirements (coated, painted, plated) may be required by DME. If the proposal is approved, this is the only authorized packaging method for the product.

  Trial and pre-production parts, service parts, and special order parts shall be packed according to the approved proposal unless otherwise approved by the DME Purchasing Representative.
  Suppliers may not deviate from shipping the quoted and approved packaging without prior authorization. Non-compliance with these requirements will influence the Delivery scoring on the Supplier Scorecard Report. The supplier may be charged for additional cost incurred for shipments that do not comply with requirements.

- **Corrosion Prevention**

  It is critical the appropriate measures be considered when developing a corrosion inhibiting system. Corrosion can be caused by various circumstances, many of which are inherent to manufacturing, handling and shipping processes. Corrosion inhibiting materials, such as Volatile Corrosion Inhibitor (VCI), Rust Preventative (RP) oil, Paint, etc., must be used where rusting and corrosion is a risk. When developing a corrosion inhibiting system for your parts, it is recommended the following measures be considered: component material properties (ferrous steel, etc.), part surface cleanliness and dryness (pack only dry and clean parts), part temperature (if possible, look to insure parts are ambient temperature before packaging), handling process (wear clean, lint free gloves when handling parts) and environmental conditions of the supply chain (temperature, humidity, volatility of climate conditions, storage conditions, transportation mode, etc.). Look to prevent part to wood, paper or corrugate contact to prevent acidic contamination that can cause corrosion. Suppliers who are in need of support to establish the appropriate corrosion protection method may wish to contact a third party who specializes in corrosion management/protection products and services.

FA-SPAP Samples shipped independently or using the same transport method as product parts must be clearly labeled and marked as "FA-SPAP Samples - Attention QUALITY HOLD" using the FA Shipping label. The FA Shipping Label in provided in the Submittal package.

8) Performance / Durability Test Data

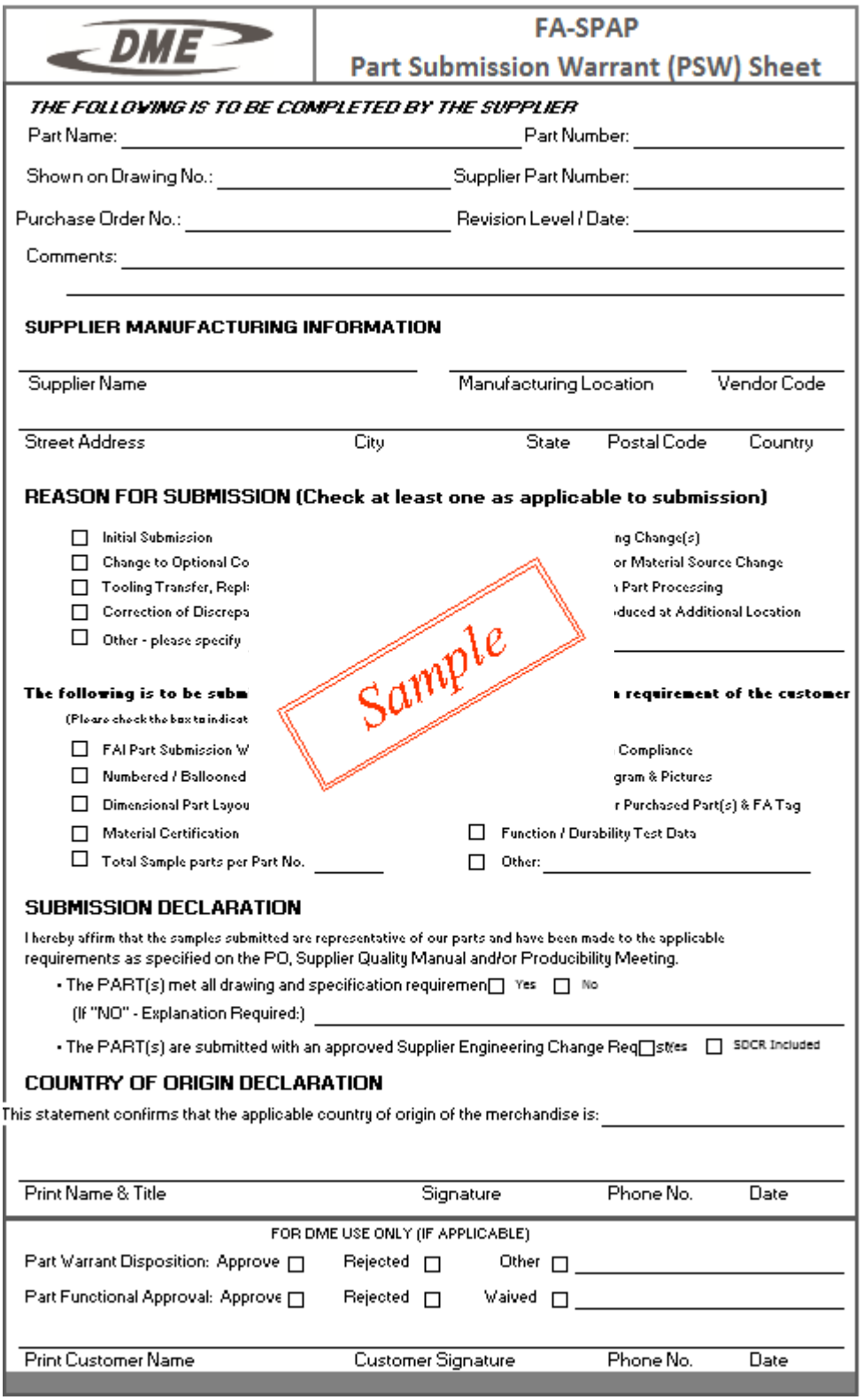
When requested, the supplier must provide the specified Performance / Durability test report(s). This report must include the type of testing to be conducted, Equipment used for testing, specified material and/or physical requirements, and the inspection/test results. A simple statement that the Performance / Durability of the part meets the requirements is not acceptable. Each report must be traceable to the supplier's part, and must be signed by the organization that performed the testing.

Performance / Durability data should be included on a format that allows for clear interpretation of the results.

9) Part Specific Requirements

This section will list part specific requirements necessary for submission of the part

Appendix 4 – Part Submission Warrant (PSW)



DME

FA-SPAP

Part Submission Warrant (PSW) Sheet

THE FOLLOWING IS TO BE COMPLETED BY THE SUPPLIER

Part Name: _____ Part Number: _____

Shown on Drawing No.: _____ Supplier Part Number: _____

Purchase Order No.: _____ Revision Level / Date: _____

Comments: _____

SUPPLIER MANUFACTURING INFORMATION

Supplier Name | Manufacturing Location | Vendor Code

Street Address | City | State | Postal Code | Country

REASON FOR SUBMISSION (Check at least one as applicable to submission)

- ☐ Initial Submission
- ☐ Change to Optional Co
- ☐ Tooling Transfer, Repl
- ☐ Correction of Discrepa
- ☐ Other - please specify

ng Change(s)
or Material Source Change
Part Processing
duced at Additional Location

Sample

The following is to be subm **requirement of the customer**

(Please check the box to indicat

- ☐ FAI Part Submission W
- ☐ Numbered / Ballooned
- ☐ Dimensional Part Layou
- ☐ Material Certification
- ☐ Total Sample parts per Part No. _____

Compliance
gram & Pictures
r Purchased Part(s) & FA Tag

- ☐ Function / Durability Test Data
- ☐ Other: _____

SUBMISSION DECLARATION

I hereby affirm that the samples submitted are representative of our parts and have been made to the applicable requirements as specified on the PO, Supplier Quality Manual and/or Producibility Meeting.

- The PART(s) met all drawing and specification requiremen ☐ Yes ☐ No

(If "NO" - Explanation Required:) _____

- The PART(s) are submitted with an approved Supplier Engineering Change Req ☐ s ☐ Yes ☐ SDCR Included

COUNTRY OF ORIGIN DECLARATION

This statement confirms that the applicable country of origin of the merchandise is: _____

Print Name & Title | Signature | Phone No. | Date

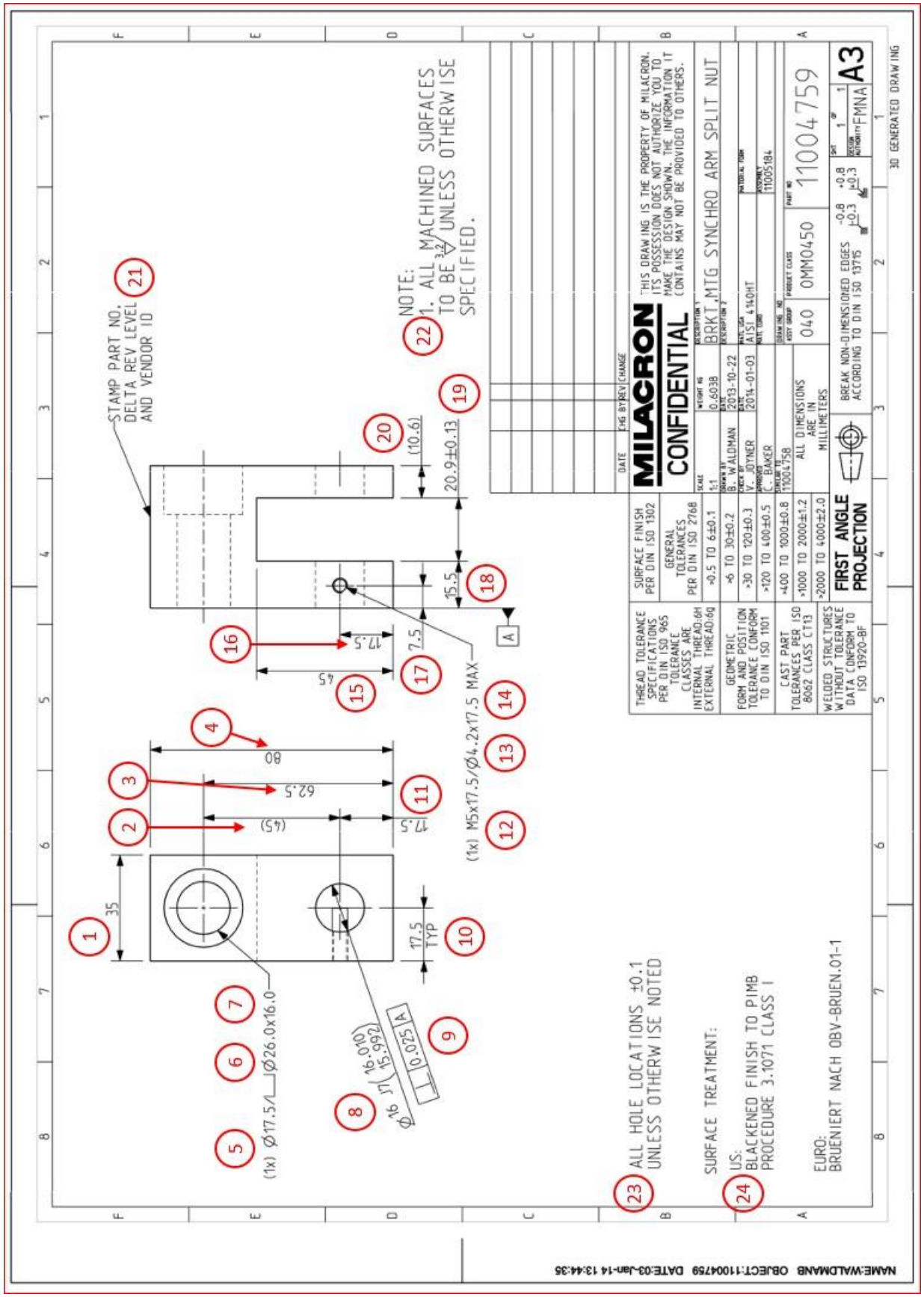
FOR DME USE ONLY (IF APPLICABLE)

Part Warrant Disposition: Approve ☐ Rejected ☐ Other ☐ _____

Part Functional Approval: Approve ☐ Rejected ☐ Waived ☐ _____

Print Customer Name | Customer Signature | Phone No. | Date

Appendix 5 – Balloon Drawing (Example)



MILACRON

FIRST ARTICLE DIMENSIONAL INSPECTION (3 Parts)

DME

Part No:	11004759	**Part Name:**	BRKT, MTG SYNCHRO ARM SPLIT NUT
Date:	5-Jan-2015	**Drawing / Revision #:**	11004759 / (no revision number on print)
Insp.by:	John Smith	**Purchase Order #:**	O3_298146

Nominal= Specification Aim
LSL= Lower Spec Limit
USL= Upper Spec Limit

Dimensions Measured in: mm

Disposition = ☐ Approved ☑ Failed ☐ Deviate ☑ Resubmit

Failed - Part 3

Dimension #	Description / Characteristic	Specification			Measurement Method / Equipment Used	Supplier Inspection Result			In Spec?	DME Inspection Result			In Spec?	Comments and Verification Details
		Nominal	LSL	USL		Part 1 Actual	Part 2 Actual	Part 3 Actual	Yes / No	Part 1 Actual	Part 2 Actual	Part 3 Actual	Yes / No	
1	linear dimension	35.0000	34.7000	35.3000	CMM, Dial Calipers	34.9000	34.9000	35.1000	Yes					
2	linear dimension	45.0000	44.9000	45.1000	CMM, Dial Calipers	45.1000	45.0000	45.2000	NO					Part 3 - evidence of part movement in setup
3	linear dimension	62.5000	62.4000	62.6000	CMM, Dial Calipers	62.6000	62.5000	62.7000	NO					Part 3 - evidence of part movement in setup
4	linear dimension	80.0000	79.7000	80.3000	CMM, Dial Calipers	80.1000	80.1000	80.1000	Yes					
5	Diameter (1x) Ø17.5	17.5000	17.3000	17.7000	Bore Gage, Pin Gage	17.5500	17.6000	17.6000	Yes					
6	Counter Bore Diameter Ø26.0	26.0000	25.8000	26.2000	Bore Gage, Pin Gage	25.9000	26.0000	25.9000	Yes					
7	linear dimension	16.0000	15.8000	16.2000	CMM, Dial Calipers	16.0500	16.1000	16.1000	Yes					
8	Diameter Ø16	16.0000	15.9920	16.0100	Bore Gage, Pin Gage	16.0005	16.0005	16.0005	Yes					
9	Perpendicularity ⊥ 0.025 A	0.0000	-0.0250	0.0250	CMM, Dial Calipers	0.0150	0.0155	0.0160	Yes					
10	linear dimension	17.5000	17.4000	17.6000	CMM, Dial Calipers	17.4500	17.4800	17.4800	Yes					
11	linear dimension	17.5000	17.4000	17.6000	CMM, Dial Calipers	17.5000	17.5500	17.5400	Yes					
12	Thread dimension M5x17.5	17.5000	17.3000	17.7000	Thread Gage	17.5500	17.5500	17.5600	Yes					
13	Diameter Ø4.2	4.2000	4.1000	4.3000	Bore Gage, Pin Gage	4.2500	4.2000	4.2300	Yes					
14	linear dimension	17.5000	17.4000	17.6000	CMM, Dial Calipers	17.5000	17.5500	17.5400	Yes					
15	linear dimension	45.0000	44.7000	45.3000	CMM, Dial Calipers	45.2000	45.1500	45.2500	Yes					
16	linear dimension	17.5000	17.3000	17.7000	CMM, Dial Calipers	17.5000	17.5500	17.5400	Yes					
17	linear dimension	7.5000	7.3000	17.7000	CMM, Dial Calipers	7.4500	7.4700	7.4500	Yes					
18	linear dimension	15.5000	15.3000	15.7000	CMM, Dial Calipers	15.6500	15.6000	15.6000	Yes					
19	linear dimension	20.9000	20.7700	21.0300	CMM, Dial Calipers	20.8550	20.8600	20.8550	Yes					
20	linear dimension	10.6000	10.4000	10.8000	CMM, Dial Calipers	10.5500	10.5500	10.6000	Yes					
	Remaining Print items on Visual Attribute Inspection Form													

FIRST ARTICLE VISUAL INSPECTION

Part No:	11004759	**Part Name:**	BRKT, MTG SYNCHRO ARM SPLIT NUT
Date:	1/5/2015	**Drawing / Revision #:**	11004759 / (no revision number on print)
Insp.by:	John Smith	**Purchase Order #:**	O3_298146

Disposition = ☐ Approved ☑ Failed ☐ Deviate ☑ Resubmit

Failed - Part 3

Dimension #	Attribute Specification	Supplier Inspection Result	Meets Spec?		Milacron Result	Meets Spec?		Comments
		Actual	Yes	No	Actual	Yes	No	
21	STAMP PART NO. DELTA REV LEVEL AND VENDOR ID	Confirm Laser Etch of information	X					
22	SURFACE TREATMENT: US: BLACKENED FINISH TO PIMB PROCEDURE 3.1071 CLASS 1	Profilometer ; Standard bar Stock finish	X					
23	NOTE: 1. ALL MACHINED SURFACES TO BE ▽ UNLESS OTHERWISE SPECIFIED.	Review Hole Dimensions for Acceptance		X				Part 3 Failed - Add Setup Fixture to assist in tight Tolerance criteria
24	ALL HOLE LOCATIONS ±0.1 UNLESS OTHERWISE NOTED	Confirm Blackened Finish	X					

Appendix 7 - Supplier Deviation and Changes Request Information

- **Supplier Deviation Request (Section of the SDCR)**

  A supplier is never permitted to knowingly ship product that deviates from the print, specification limits, or design intent without written authorization from DME. If such a condition exists, the supplier may request DME to allow shipment of the product. This is accomplished by initiating a Deviation Request. A new deviation form has to be submitted for each shipment of deviated parts.

  If directed by DME, the supplier must send samples of non-conforming items to DME for evaluation. The cost of any testing required to determine the acceptability of the product will be charged to the supplier. DME will determine the item's acceptability and what corrective actions (if any) are required beyond the deviation. If approved, DME will send a written deviation approval to the supplier.

  The deviation is only intended to be an interim action and is not to be construed as an engineering change. The supplier must begin work immediately to correct the condition in question. This must be accomplished within the time frame stated on the deviation. Failure to comply with the mutually agreed upon closure date for the deviation may result in the supplier's rating being affected.

  In all cases, the supplier must fully contain all product suspected of being non-conforming at their facility. In addition, the supplier may be required to sort any suspect product at DME.

  Any parts sent to DME that have been approved on a Deviation must be clearly identified on the box, container, or other packaging method with the appropriate markings decided jointly by DME and the supplier. Reference Appendix 8

- **Supplier Change Request (Section of the SDCR)**

  A Supplier Process Change Request (SCR) is used to request a change to a released part, process, drawing, specification or material. DME encourages SCRs for process improvement with the stipulation that before an SCR is submitted, the supplier thoroughly reviews their plan to assure that all process-related issues have been addressed and resolved.

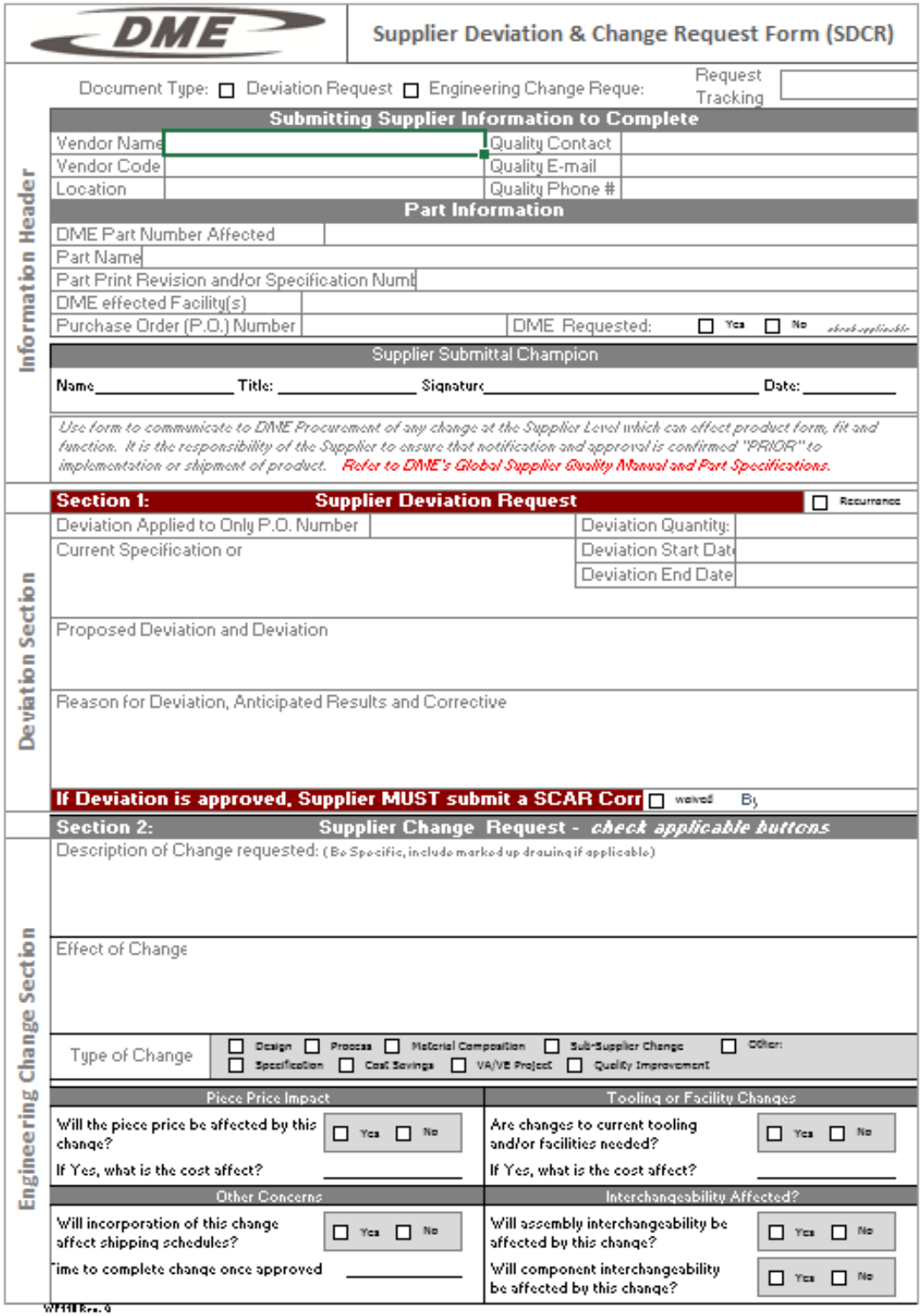
  The originator of an SCR includes the following information:
  - Drawing or part number
  - Drawing or part title
  - Description of problem or recommended change
  - Reason for change or "rationale"
  - Proposed effective date

  The supplier submits the SCR with the revised FMEA and control plan (if applicable) to DME for evaluation of the following:
  - Supplier-demonstrated process capability and stability
  - Comparison to First Article data
  - Industry standards
  - Supplier process engineering capabilities
  - Supplier's adherence to control plan

  After DME has completed the review, and concurs with the supplier, DME will notify the supplier as to the final disposition of the SCR and part submittal requirements and dates.
  Reference Appendix 8

  When monitoring is required, the appropriate markings must be identified on the lots etc. for a specified time frame as decided jointly with DME and the supplier.

Appendix 8 - Supplier Deviation and Change Request Form Example



DME

Supplier Deviation & Change Request Form (SDCR)

Document Type: ☐ Deviation Request ☐ Engineering Change Reque: Request Tracking

Information Header

Submitting Supplier Information to Complete

Vendor Name		Quality Contact	
Vendor Code		Quality E-mail	
Location		Quality Phone #	

Part Information

DME Part Number Affected			
Part Name			
Part Print Revision and/or Specification Numb			
DME effected Facility(s)			
Purchase Order (P.O.) Number		DME Requested:	☐ Yes ☐ No check applicable

Supplier Submittal Champion

Name_____ Title: _____ Signature_____ Date: _____

Use form to communicate to DME Procurement of any change at the Supplier Level which can effect product form, fit and function. It is the responsibility of the Supplier to ensure that notification and approval is confirmed "PRIOR" to implementation or shipment of product. *Refer to DME's Global Supplier Quality Manual and Part Specifications.*

Deviation Section

Section 1: Supplier Deviation Request ☐ Recurrence

Deviation Applied to Only P.O. Number		Deviation Quantity:	
Current Specification or		Deviation Start Date	
		Deviation End Date	

Proposed Deviation and Deviation

Reason for Deviation, Anticipated Results and Corrective

If Deviation is approved, Supplier MUST submit a SCAR Corr ☐ waived By

Engineering Change Section

Section 2: Supplier Change Request - *check applicable buttons*

Description of Change requested: (Be Specific, include marked up drawing if applicable)

Effect of Change

Type of Change: ☐ Design ☐ Process ☐ Material Composition ☐ Sub-Supplier Change ☐ Other: ☐ Specification ☐ Cost Savings ☐ VA/VE Project ☐ Quality Improvement

Piece Price Impact		Tooling or Facility Changes	
Will the piece price be affected by this change?	☐ Yes ☐ No	Are changes to current tooling and/or facilities needed?	☐ Yes ☐ No
If Yes, what is the cost affect?	_____	If Yes, what is the cost affect?	_____
Other Concerns		**Interchangeability Affected?**	
Will incorporation of this change affect shipping schedules?	☐ Yes ☐ No	Will assembly interchangeability be affected by this change?	☐ Yes ☐ No
Time to complete change once approved	_____	Will component interchangeability be affected by this change?	☐ Yes ☐ No

D-M-E

D-M-E Company
29111 Stephenson Highway
Madison Heights, MI 48071

Supplier Corrective Action Request

Number: **MH 3906** Date: **2/22/2018**

Supplier:

SAMPLE SUPPLIER (00000)
12345 ANY STREET
DETROIT, MI 480801234

Reply Required By
3/24/2018

Initiator:

Ken Sawka
Quality Assurance - Mechanical
Phone: (248) 544-5062
Fax: (248) 544-5467

Attn:

Control plan has been reviewed for adequacy by: _____ Date: _____

Part Number: **TEST** **FOR REVISION PURPOSE** Print No.:

P.O. No.: Quantity Received: **0** Quantity Rejected: **0**

Description of Discrepancy

I.N.: 0 - Quality 2

○ Returned for Rework ○ Rework at Supplier's Expense ○ Debit Memo to Follow ○ Used As Is
○ Returned for Evaluation ○ Repaired by D-M-E Other:

Adam Marano
Regional Quality Manager - DME

Jim Hunt
Planner

Supplier response required by date shown above.

Please include short term C.A., suspected root cause, permanent / long-term C.A., and expected date of permanent C.A. Use area provided below or add another page if necessary.
Provide objective evidence if available

Signature _____ Title _____ Date _____

Print Name _____ Phone _____ Email _____

WF109 Rev. F Ref. WP028 File: SQASFORM!CarReport

Appendix 10 - Supplier Corrective Action Expectations and Required Deliverables

The supplier's corrective action response should follow a problem solving methodology similar to the process outlined below, but not limited too. The focus should be on identifying the root cause(s) of the problem and taking action to prevent its recurrence. The utilization of pictures throughout the corrective action process is required in order to aid in communication and visualization of steps taken for resolution and prevention. This is specifically important due to the diversity of DME's Global Supply Chain.

1. Select a Problem Solving Strategy / Team

Based on the problem's complexity, establish a team with the product / process / people knowledge, skills, and authority to resolve the problem and implement corrective actions. The team will monitor and document the process and oversee the problem's successful and permanent resolution.

a. A team is made up of more than one person.

2. Define and Describe the Problem

Problem description shall include the non-conforming failure condition as reported by DME and any further processing environment understood by the supplier. It shall include the number of parts involved and dates or date codes of the parts.

The team will develop a problem definition, which identifies the difference from the expected ("should") performance and the "actual" performance of the part. Narrow and focus the definition by applying specific **"5W"** factors **(Who, What, When, Where, Why)**. Define the goals and measurements for an improved process.

a. Confirm document references DME part number
b. Define problems in detail and quantifiable terms
c. Identify the requirement that is defective. Must include the specified requirements and the actual condition.
d. Identify when the problem started
e. List manufacturing dates of defective material

3. Protect the Customer through Containment Action(s)

Take immediate actions to isolate the effect of the problem from DME until permanent corrective action(s) are implemented. Verify that these containment actions are effective. Interim action shall include estimated or actual timing for implementation. Interim action is typically containment oriented and is usually accomplished via 100% inspection. Identify what actions were taken to isolate the effect of the problem.

a. Define and verify Interim Containment Actions
b. All stock locations must be reviewed and re-inspected
c. Describe method of sorting including the method for identifying the status of the material. Provide daily sort results, if applicable
d. Stock replacement strategy identified and implemented
e. Validate effectiveness of Internal Containment Action

4. Identify and Evaluate Root Cause(s)

Root causes are weaknesses, ineffective processes or controls, in a Quality Management System that cause or allow (fail to prevent) errors and nonconformance's. As an aid to determining the root cause, define the current process using process mapping techniques that include:

Inputs (internal / external supplier requirements)
Process (internal actions depicted by a flowchart)
Outputs (internal / external customer requirements).

Also define the customer-driven desired outcomes and performance goals / measurements for an improved process.

Identify potential root cause(s) of the problem using the multiple tools like: Process mapping, “Go to See”, 5W / 2H, “is / is not” comparisons, cause-and-effect diagrams, brainstorming, process analysis, FMEA, flow diagrams etc. Evaluate the potential root causes through data collection, testing and analysis using evaluation tools like: check sheets, histograms, Pareto charts, SPC charts, scatter plots, etc.

A root cause shall be fully investigated and defined - not just a superficial analysis. The initially reported root cause(s) may change as the investigation progresses. What was initially believed to be a root cause may turn out to just be one of the symptoms or immediate causes, so further investigation is needed.

Immediate causes are NOT root causes. Typical immediate causes you may see on Corrective Action reports are:

- Operator error
- Operator not trained
- Failure to follow procedures/work instructions
- Inadvertent omission
- Gage not turned in for calibration
- Work instructions not updated
- Inspection not recorded by the operator

The final report shall indicate the ultimate root cause(s). Root Cause analysis attempts to get at the heart of the problem so that it can be fixed and prevent recurrence. It is recommended that you keep evidence of how you determined the Root Cause in case the first solution does not work. You can then refer back to your notes to select another possible root cause without having to go through the whole process again.

a. Consider multiple root causes
b. Define in detail the root causes(s)
c. Team to be fact- based and data driven in defining root causes.
d. Verify the root cause
e. Address the Escape Point (Place in the process where the effect of the root cause should have been detected and contained).
f. The method to contain the issue causing the defect until corrective action is implemented and proven effective.
g. Use the 5 Why approach, or other effective method for documenting the approach
h. Permanent Corrective Actions must address the root cause and the Escape Point
i. Actions such as “train the operator,” “discipline the operator,” or “increase inspection,” are typically not acceptable corrective actions.
j. Must be very detailed. Describe who will do what and how it will be implemented and when.
k. Establish ongoing controls that will verify the effects of the corrective actions
l. Verify and validate the corrective actions. Describe in detail the method of verification.

5. Determine and Implement Permanent Corrective Action(s)

Create and evaluate the effectiveness of the proposed solution alternatives designed to eliminate the root cause(s). Implement the best permanent corrective action solution(s) through process and / or product changes with on-going controls to ensure that the root cause(s) are eliminated. All relevant documentation that is affected to standardize corrective actions into the supplier’s quality system needs to be updated. Permanent Actions shall include estimated or actual timing for implementation. Permanent action is of a preventative nature and is typically process oriented.

a. Determine the permanent corrective actions
b. An effective corrective action will PREVENT recurrence or REDUCE THE FREQUENCY of occurrence.
c. Evaluate undesirable side effects, including costs
d. Confirm that the root cause has been address and not just the contribution cause(s)
e. How will we monitor the success of the actions
f. Has training been developed to support the corrective action(s)

6. Verification

Verification shall include data, which indicates both before and after levels of performance, thereby substantiating the results and effectiveness of the action taken. This applies to both Interim and Permanent actions.

a. Objective Evidence of all action taken is required to be submitted with SCAR responses i.e. revised processes sheet, tooling changes, gage changes etc.

7. Modify the Documents and System(s) to Prevent Recurrence

Modify all systems, procedures, processes and provide appropriate training to **prevent** the recurrence of this and similar problems. Document these changes and distribute to other potentially affected areas and similar parts. Monitor and measure the process on a continuing basis to ensure there are no repeat problems, and that all improvements are maintained.

a. Modify necessary policies and procedures to prevent reoccurring problem
b. Evaluate whether corrective actions can be implemented on similar products or processes.

8. Closure of the corrective action request

Confirm successful closure of the closed-loop corrective action process. Complete editing of SCAR document and photos for final submittal. Confirm all team members are listed and submit all evidence with form to DME. Recognize the success of the dedicated and cooperative efforts of all team members in permanently solving the problem.

Appendix 11 - Supplier Monitoring Methods

1) Supplier Scorecard & Performance Evaluations

DME monitors and ranks its suppliers using a supplier scorecard. The output of the supplier scorecard is used by the DME Procurement and Quality teams to determine opportunities to grow business and to determine opportunities for supplier improvement. The supplier scorecard is comprised of 4 major elements: Quality, Delivery, Lead Time and Payment Terms.
Scoring is based on a 100 point scale and is tallied monthly. The Total score is out of 100 points. *(See the DME's Supplier Rating System Scale)*

DME maintains records in order to evaluate suppliers. Consideration for the continuation, expansion or termination of business is based on these evaluations. Examples of such records are:

- Defects to Receipt/PPM of non-conforming material (The Goal is 0 PPM)
- Quality Alert and Supplier Corrective Action Request (SCAR)
- Stop shipment due to quality concerns
- Supplier responsiveness to quality issues
- Effectiveness of Corrective Action
- 100% on-time delivery with required quantities

Written corrective actions shall be required if a supplier's performance fails to meet expectations for either quality or delivery. Supplier and/or sub-supplier audits may be conducted to re-evaluate their status as approved suppliers to DME

Supplier Rating System

Scoring Category	Metric Scale	Points
Quality (40 points)		
Defect Quantity (Monthly & YTD)	0 - 5 units	20
	6 - 25 units	18
	26 - 50 units	16
	51 - 100 units	14
(Order of Magnitude)	101 - 200 units	12
	201 - 300 units	10
	301 - 400 units	8
	401 - 500 units	6
	501 - 750 units	4
	751 - 1000 units	2
	1001 < units	0
Impact Quality Indicator (IQI)	0 to 5 quality occurances	20
Number of Quality Occurances (Monthly & YTD)	6 to 10 quality occurances	16
	11 to 15 quality occurances	12
	16 pts to 25 quality occurances	8
(Order of Frequency)	26 pts to 50 quality occurances	4
	51 pts to 75 quality occurances	2
	76 and greater quality occurances	0
Delivery (20 points)		
% On-Time to Supplier Promise Date (Monthly & YTD)	90% - 100%	20
	80% - 89%	16
	70% - 79%	12
	60% - 69%	8
	50% - 59%	4
	25% - 49%	2
	0% - 24%	0
Lead Time(20 points)		
Variance to Milacron Target (Monthly & YTD)	0 or less than	20
	>0 to 2	16
	>2 to 5	12
	>5 to 10	8
	>10 to 15	4
	>15 to 20	2
	>20	0
Payment Terms (20 points)	(2% 20 days Net 60)	
Variance from 2%	2% or greater	8
	1.5% - 1.99%	6
	1.0% - 1.49%	4
	0.50% - 0.99%	2
	0% - 0.49%	0
Variance from 20 days	20 days equal to or less than	2
	21 days or greater then	0
Variance to Net 60	60 days or greater	10
	50 - 59 days	8
	40 - 49 days	6
	30 - 39 days	4
	20 - 29 days	2
	0 - 19 days	0
Commercial (Rating)		
Net Material Economics	Improved Economics from last year to this year	G
	Flat Economics from last year to this year	Y
	Degraded Economics from last year to this year	R

2) OTD (On Time Delivery)

DME measures OTD globally throughout the supply base. Results are periodically reviewed to identify supplier delivery trends that will or are negatively impact DME. Actions will be taken to realign the delivery trends to a favorable state with the supplier.

OTD World Wide Delivery Window Measurement Criteria

+2 working days = the supplier should not deliver the goods later than the order confirmation date

-5 working days = the supplier should deliver the goods max 3 working days before the confirmed date

3) Supplier Audits

Periodically, DME may audit the supplier's quality management system and/or part production process. The supplier must make their facility available for on-site process verification by DME personnel at any time, with reasonable notice. This may be a full or abbreviated documentation and on-site audit. The purpose is to evaluate any changes that may have occurred in the supplier's quality management system and/or part production process, and to assess the supplier's continuing commitment to quality improvement.

4) Incoming Quality Control / Receiving Inspection Audits

DME expects its suppliers to furnish material that conforms to all requirements, and that does not need to be inspected when DME receives it.

DME may apply the use of incoming quality control in order to verify the conformity of supplied parts to agreed specifications. This may include identity checks, or checking for agreed corrections to critical parts. Unless otherwise previously agreed, the conformity of incoming goods is evaluated against agreed DME specifications or drawings as well as other relevant standards according to the commodity purchased.

DME may inspect product at the supplier's facility to detect potential problems prior to shipment and may also inspect product at sub-tier suppliers.

5) Nth Article Inspection

DME may require the supplier to perform an annual Nth Article inspection of each critical part to verify continuing conformance of the part to the specification. This is also required if an engineering change affecting form, fit, or function occurs. The Nth Article requirement is not applicable to non-critical parts.

For all sub-components, the manufacturing supplier is responsible to ensure that the components that make up each assembly are qualified and monitored through the supplier's own part qualification system.

At the discretion of DME, Nth Article can be postponed beyond, or required prior to, the annual expiration. Considerations such as component volume, program life cycle and supplier/part performance are used in the decision to pull in or extend the requirement for Nth Article.

6) Supplier-Furnished Lot Documentation

DME may require the supplier to furnish inspection, test, process performance, or other quality data with each shipment to ensure that the product meets DME's requirements. When data submission is required, the data must accompany each shipment, or be e-mailed or faxed to DME at the same time the lot is shipped. All documentation must be clearly identified with DME's part number, and the supplier's lot number

Contact Global Facility Location for Specific Regional Addendums

EUROPEAN ADDENDUMS to GSQM:

2.0 SUPPLIER QUALIFICATION/ASSESSMENT PROCESS (continued)

2.1 RFI – Request for Information

Supply Chain Manager (SCM) addresses supplier via e-mail. DME is introduced (link to web site and/or Online Commercial Communications (ex.YouTube)). RFI structured form is preparing and will be available in valid version on SPES SharePoint. RFI form included:

- Expressing – Interest in cooperation and free production capacity confirmation
- Information about supplier (Legal Entity, Manufacturing Sites Footprint, Technology capabilities, Financial Stability)

Furthermore, the willingness to meet DME's requirements – the QCDS rating and respecting the contract agreements – are evaluated.

2.2 On-site assessment

RQM in collaboration of SCM decide what type of supplier we are going to assess to get it on Preferred Supplier List (PSL). There are two major categories of suppliers:

- **Category 1** Custom part (made to print) suppliers as well as Service suppliers which adds added value to DME product
- **Category 2** Standardized component suppliers (bearings, fasteners, sensors etc.), indirect and services (MRO).

2.3 Supplier Qualification Criteria:

Category 1 – follows supplier qualification process as per flow chart no. XXX (AS PER APPENDIX 2) and bullet points below.

- Supplier On-Site Assessment is must
- Good level of pricing policy
- Good level of delivery performance
- Good level of quality performance
- Good communication level
- Applicable Part Validation Process
- Flexibility

Category 2 – those suppliers have to fulfil following criteria, those suppliers follows **simplified** way of supplier qualification according flow chart no. XXX (AS PER APPENDIX 2):

- ISO 9001 certification
- Good level of pricing policy
- Good level of delivery performance
- Good level of quality performance
- Good communication level
- Applicable Part Validation Process
- Flexibility

Level targets as per bullet points above for both supplier categories might differ based on supplier character (commodity) and is defined by strategic sourcing department.

2.4 Supplier Self-Assessment (SA)

RQM defines whether self-assessment (SA) needed based on supplier type, available time frame and its overall character.

Conditions when SA needed:

- Always during new tenders where data quality level of supplier's SA helps to understand what supplier to select and later assess in its facility.
- Always in case if the supplier has not been visited by RQM

yet Conditions when SA not needed:

- It is a case of service supplier (e.g. Surface Treatment suppliers)
- Available time frame does not allow to perform this step (urgent assessments)

RQM approaches supplier with request of SA 2 or 3 weeks prior On Site Assessment (OSA). For this purpose uses document F063 DME ON-SITE ASSESSMENT QUESTIONAIRE (OSA tool).

For this purpose he/ she uses OSA questionnaire which is available for download on intranet DME Magic in section.

Link to DME Magic:

TBA

Link to Document Library:

http://intranet.DME.com/spes/_layouts/15/start.aspx#/SPE%20DATABASE/Forms/AllItems.aspx RQM takes care of to make sure the SA will be provided by the supplier on date set by him/her. He/She also verify quality of provided SA data and makes following decision:

- Data quality provided by the supplier is not good enough and supplier has to correct its SA and re-submit again still prior the OSA.
- It is clear the supplier does not understand the content of SA or there is a language barrier, then RQM decides to put the supplier on so called "Do Not Source List" (Exceptions possible if Team of SCM and RQM agrees otherwise)
- Data quality is good, OSA will be planned
- SA score might influence which supplier selection for given projects. RQM and SCM agrees who will be those suppliers.

2.5 On-Site Assessment (OSA)

Date of OSA is planned in advance and is sent in the e-mail requesting SA. Supplier has to confirm their availability on that planned assessment date.

RQM provides assessment agenda. This Assessment Agenda follows DME ASSESSMENT QUESTIONAIRE. Supplier assessment is performed according this plan and at the end of the assessment day RQM performs assessment wrap-up and announce estimated assessment result.
The supplier can reach following assessment result:

- Passed the audit
- Conditional Pass
- Rejected or Hard development possible

Final Assessment Result is targeted to be communicated within two weeks from assessment date by email and the supplier has the same time scale for action plan submission.

This has to be in form of CONTINUAL DEVELOPMENT ACTION PLAN (This is not valid for suppliers who PASSED the assessment)

This announcement email has to include:

- Exact assessment score in %
- Completed Supplier Assessment Questionnaire by the assessor
- Non-Conformity list (Separate tab in OSA) and their level of criticality
- Planned Due Date ofSupplier Development closure furthermore due date of supplier re-assessment (Valid only for Soft Supplier Development – SSD)

2.6 Periodic Reevaluation Existing Suppliers

DME periodically reevaluates current production suppliers through the use of quality performance data and/or on-site assessments. A Supplier Evaluation Team, consisting of Purchasing and Quality Representatives may be utilized to gather the appropriate data to evaluate the Suppliers. If requested, the supplier shall make their facility available for on-site process verification by DME personnel, with reasonable notice. Once completed, it will be determined whether the existing Supplier has the required quality systems, technical core competencies and financial stability to be awarded additional business. Once the supplier Passes the assessment or finalizes Supplier Development he should be re-qualified within reasonable time period again.