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# **EMS Mission Statement**

Our mission is to be recognized as the world's leading supplier of clad metal products. Through our intense focus on customer satisfaction and our unique knowledge of material technology, we will develop innovative, reliable, and cost effective solutions. We will accomplish this by building lasting relationships with our employees, customers, and suppliers.

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## 0.1 General Introduction

This quality manual serves as the guiding document towards the capabilities of the EMS Business Processes for the manufacture of Bi-Metal Strip and Parts, and Clad Materials. Applicability commences with the receipt of customer orders and concludes with their acceptance of the product, documentation, and data agreed to in the initial customer order. This manual provides a description of the quality management system in accordance with the ISO 9001:2008 requirements and serves as a reference for implementing and maintaining the system.

## 0.2 Process Approach

EMS has developed and implemented its quality management system using the process approach as described in this manual. To function effectively and efficiently, the EMS organization identifies customer requirements and manages activities and resources for planned inputs to yield effective and value added outputs for product realization as a business process. Outputs from one segment of the process directly provide the inputs to the next segment as the basis for a systematic process approach. A process approach provides ongoing control over the linkages between the individual processes, resources and the interactions between them to assure the realization of business objectives. It provides for continual improvement of processes based on objective measurement.

## 0.3 Process Model

## Continual Improvement of the Quality Management System

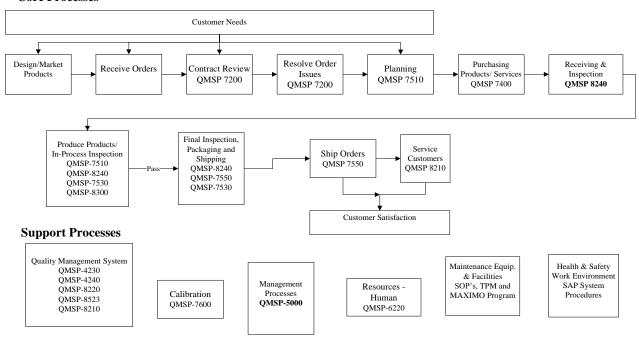
#### **Management Responsibility** Measurement, Analysis & Resource **Financial** Management Improvement **Planning** Review Management Product Resource & QMS Data Needs Organizational **Business Development** Planning & Satisfaction **Objectives** Repair & **Control of** Maintenance Nonconforming Product Communication **Process** Engineering Corrective & Preventive **Equipment &** Actions Facilities **Engineering** Policies & directions Internal **Audits** Resources Concerns, Surveys, Returns Product, Process & QMS Performance Data **Product Realization Product Engineering** ayment **Invoicing &** Technical/info **NBD** Collections Assistance Invoice Contract Req'ts S&OP Manufacturing Forecasts CUSTOMERS CUSTOMERS RFQ Finish Commercial Bookings 1 Backlog/Demand Plan Goods Shipping Scheduling & Materials Docs LJs/DJs Quote **Planning LOGISTICS** Production Plan Material W. H. Pricing Regts. Delivery Pack & Order Ship **Purchasing** Management Acknowledgement Rec'g Purchase Orders Materials **Customer Oriented Process Suppliers Support Oriented Process Management Oriented Process Quality Management System Procedure**

## 0.4 EMS Level 2 Process Flow Model

The QMS Process System Flow Chart showing the interaction between processes is presented below:

## **Process Model**

#### **Core Processes**



## **Level II Documents**

| QMSP 4230 – Control of Documents                                       | QMSP 4240 – Control of Records                        |
|--|---|
| QMSP 5000 - Management Responsibility                                  | QMSP 6220 – Competence, Awareness and Training        |
| QMSP 7200 – Contract Review  | QMSP 7400 – Purchasing                                |
| QMSP 7510 – Control of Production Provisions and Work Instructions     | QMSP 7530 – Product Identification and Traceability   |
| QMSP 7550 – Handling, Storage, Packaging,<br>Preservation and Delivery | QMSP 7600-Control of Measuring and Monitoring Devices |
| QMSP 8220 – Internal Quality Audits                                    | QMSP 8210 – Customer Satisfaction                     |
| QMSP 8300 – Control of Non-conforming Product                          | QMSP 8240 – Inspection and Test                       |
| QMSP 8523 – Corrective and Preventive Action                           | QMSP 8600 – Continual Improvement                     |

# 1.0 Scope

This quality manual scope demonstrates the capability and continual improvement of the EMS business process for the manufacture of Bi-Metal Strip and Parts, and Clad Materials. Applicability commences with the receipt of customer orders and concludes with their acceptance of the product, documentation, and data agreed to in the initial customer order.

1.1 Quality Management System (QMS) Compliance

The purpose of this Quality Manual is to define and describe the Engineered Materials Solutions, LLC (EMS) Quality Management System (QMS), the management authority and responsibility involved in the operation of the system, and to provide policy for all activities comprising and using the quality system. This is communicated and understood at all levels of the organization. This quality manual presents the quality management system to our customers and other external parties, informing them of the specific controls implemented by the business to assure quality of supplied products.

The quality management system is relevant to the nature of our organization and products, and to consistently meet customer and regulatory requirements. Customer satisfaction is achieved through this process and the continual improvement of this process

This quality system complies with the following international standards:

## 1.2 Application

The following requirements of ANSI/ISO/ASQ Q9001-2008 are excluded from the EMS quality management system. The exclusion does not preclude the organizations ability to provide product that meets customer and regulatory requirements.

## **Excluded**

There are no Service Provisions for EMS as noted in Section – 7.2.1a and 7.5.1f

## 7.0 Normative Reference Documents

2.1 Reference Standards

**ISO 9000:2005**: Quality Management Systems – Fundamentals and Vocabulary

**ISO 9001:2008**: Quality Management Systems – Requirements

**ISO 9004:2009**: Managing for the sustained success of an organization – A quality management

approach

## 3.0 Terms and Definitions

For the purposes of this document the terms and definitions given in ISO9000 apply.

## 3.1 Quality Policy

EMS management has created and disseminated the following Quality Policy to provide the organization with an understanding of management's commitment to Quality:

Engineered Materials Solutions, LLC is committed to fully meeting customer requirements and continuously improving Product Quality, Service and the Total Cost of Ownership. This Policy will be achieved through disciplined process based management and employee participation across the organization towards continual improvement.

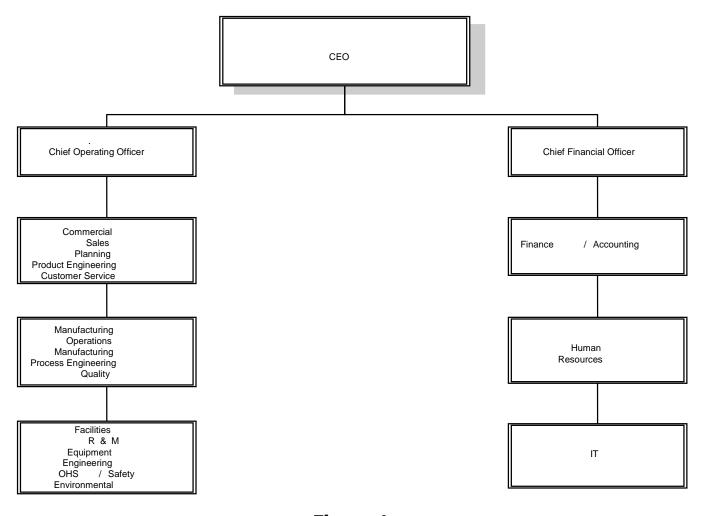
## 3.2 Organization

EMS is a privately owned business part of the Wickeder group operated by the EMS CEO and the EMS Board of Directors. The EMS Executive Organization is shown in **Figure 1**.

In order to most effectively serve the customer and to support the implementation of lean manufacturing, the EMS organization is structured into market sectored value streams. These customer value streams, **Specialty Clads** and **Bimetal** are fully staffed to provide effective planning, scheduling, manufacturing and Shipping and Handling for operations that support unique customer sector requirements.

# **EMS Executive Org Chart**

April 2 , 2012



# Figure 1

# 4.0 Requirements

## 4.1 General Requirements

The quality management system at Engineered Materials Solutions, LLC (EMS) has been established, documented, implemented, and maintained with the purpose of satisfying customers and continually improving processes and products.

To implement the quality management system, EMS:

- Identifies the processes needed for the quality management system and their application throughout the organization;
- Determines the sequence and interaction of these processes;
- Determines criteria and methods required to ensure the effective operation and control of these processes;
- Ensures the availability of resources and information necessary to support the operation and monitoring of these processes;
- Monitors, measures and analyzes these processes, and
- Takes action necessary to achieve planned results and continual improvement.

EMS manages all processes in accordance with the requirements of ISO 9001:2008. When EMS outsources any processes that affect product conformity with requirements, they are controlled as identified within the Quality Management System.

Quality and Business Performance metrics are described within annual EMS Business objectives that are generated separate from the quality manual and include among numerous performance metrics:

- Evaluation of Customer Satisfaction
- Quality Yield Performance
- Supplier Performance
- Trends in Non Conforming Products and Quality Losses
- Financial Performance
- Manufacturing Efficiency
- Safety Performance
- Quality System Analysis
- 4.2 Documentation Requirements QMS Documentation Structure
  - 4.2.1 EMS has defined the documentation, including the quality policy and quality objectives, needed to establish, implement, and maintain the quality management system and to support an effective and efficient operation and the interaction of processes. The Quality Management System documentation includes:
    - a) Level 1 Quality Manual: defines the outline structure of the quality system.
    - b) Level 2 Quality Management System Procedures (QMSP): define the operations, procedures and responsibilities that form the basis of the quality system.
    - c) Level 3 Work instructions: Include but are not limited to Standard Operating Procedures (SOP's), Standard Inspection Procedures (Sip's), Material Specifications, Route Cards and Work Instructions (WI – for EMSH) that serve to detail process requirements across the business in order to meet EMS and Customer requirements.
    - d) Level 4 Records: provide evidence that the quality system requirements are carried out suitably and effectively. Typically available but not limited to Materials and Product. Database's on line such as Oracle, Everest, Excel, etc and may include hard copy where required.
- 4.3 Quality System Overview
  - 4.3.1 The EMS Quality System is a documentation system that includes the EMS Quality Manual, that describes the general structure and philosophy of the EMS Quality System, the EMS Quality Policy, QMS Procedures that define management responsibility and basic functional area requirements, and Work Instructions (SOP's, Sip's, WI's, QSB's) that detail how the organizational processes are defined and deployed and Forms that are used to record results.
  - 4.3.2 Quality Planning

Quality planning is the responsibility of EMS organization managers, who define and document the specified requirements for products, projects, or contracts as follows:

- Preparation of quality plans and procedures.
- Identification and preparation of quality records.
- Documenting means for identifying customer requirements, both objective and subjective, and for translating those customer requirements into the production and delivery of product.

- Identification of suitable verification points at appropriate stages in the realization of the product.
- Ensuring that measurement, testing, and control equipment for assessing quality utilize recognized procedures and meet documented external standards, as appropriate to the processes in question.
- Methods for evaluating process capability that allows development of processes for meeting anticipated capability requirements.

#### 4.3.3 Document and Data Control

EMS maintains documented procedures to control documents and data that relate to the Quality System. Customer drawings and documents of external origin are also kept under revision control.

## 4.3.4 Documents and Data Approval and Issue

All document reviews, approvals, and issues are performed by the functions that are responsible for their origination, revision, or maintenance. The Process Owners responsible for specific quality related documents follow an online web based index, clearly denoting the current revision level and issue date. All current issues of the appropriate documents are accessible at user locations through the internal web page.

Obsolete documents are promptly removed from circulation. Reference documents are properly marked and archived. Hard copies are considered to be uncontrolled and revisions should be checked to the online listing for current revision.

#### 4.3.5. Engineering Specifications

Procedures assure timely review, distribution, and implementation of customer engineering standards/specifications and changes. A record of such changes includes the date when the change was made and implemented in production. The document control system includes the date that appropriate documents are updated.

## 4.3.6 Document and Data Changes

Changes to documents and data are reviewed and approved by the same functions that performed the original review and approval. The same review and approval process is used for changes as on the original documents. Nature of the change is identified in the online database.

#### 4.3 Control of Records

Documented procedures specify methods for record identification, maintenance, collection, indexing, accessing, filing, storage, and disposition. Quality records are maintained to demonstrate conformance to specified requirements and verify effectiveness of the quality system. Supplier quality records are a part of this system. Quality records are legible and stored and retained in a suitable fashion for easy accessibility and to prevent damage, deterioration, or loss. Retention times of quality records are documented in quality procedures. If required contractually, quality records are kept for a specified period and are made available to the customer for review.

#### 4.4 Record Retention

Production part approvals, tooling records, purchase orders and amendments are maintained for the entire active period of the part (or family of parts) plus one calendar year. The active period applies to regular production parts. All customer purchase orders, amendments and EMS purchase orders/amendments for customer-owned tooling are included in this requirement.

Quality performance records such as control charts and inspection/test results are retained for one calendar year after the year they were created.

Records of internal quality system audits and management reviews are retained for three years. These requirements do not supersede any government or customer requirements. All retention times are minimums.

# 5.0 Management Responsibility

## 5.1 Management Commitment

- The CEO and Top Management support the development and requisite maintenance for a Quality System. They are committed to the development and implementation of the quality management system. This is achieved by:
  - a) Communicating to employees the importance of meeting customer as well as statutory and regulatory requirements. Several channels of communication will be used including training, newsletter, employee meetings, postings on bulletin boards, etc.;
  - b) Establishing our quality policy and quality objectives;
  - c) Conducting management reviews;
  - d) Ensuring the availability of necessary resources by reviewing the workload (per QMSP 5000)

#### 5.2 Customer Focus

5.2.1 The CEO ensures that the customer needs and expectations are determined per procedures QMSP 5000, converted into requirements and fulfilled met with the aim of achieving customer satisfaction, per section 7.2.1 and 8.2.1 of this manual.

## 5.3 Quality Policy

- 5.3.1 The CEO, Management Representative have defined and approved the company's quality policy and use it as a means of leading the EMS organization toward continual improvement. This policy has considered the following:
  - a) the need to be appropriate to the purpose of EMS;
  - b) the need to include a commitment to meeting requirements and to continual improvement of QMS;
  - c) the need to provide a framework for establishing and reviewing quality objectives;
  - d) the need to be communicated and understood within EMS by training and posting on bulletin boards;
  - e) the need to be reviewed annually for continuing suitability.

The quality policy is a controlled document and is displayed on employee bulletin boards and other appropriate locations in the organization. The quality policy is reviewed annually within Management Review.

#### 5.4 Planning

#### 5.4.1 Quality Objectives

The CEO approves the quality objectives to ensure they are measurable and consistent with the quality policy and that they include the commitment to continual improvement. These quality objectives are established at relevant functions and levels, and include those needed to meet requirements for product. Quality objectives are reviewed at Management Review meetings.

## 5.4.2 Quality Management System Planning

The planning of the quality management system is carried out to meet the requirements specified in section 4.1 and the quality objectives. The quality system plan consists of

the four levels of documentation and implementation activities as defined in the documents. The Management Representative ensures that change is conducted in a controlled manner and that the integrity of the quality management system and its objectives are maintained when changes are planned and implemented.

## 5.5 Responsibilities, Authority, and Communication

## 5.5.1 Responsibility and Authority

The organization chart Figure 1 shows the organization of EMS. The Organization chart identifies functions (and cross-functions) and their interrelations within the EMS organization. EMS has defined the detailed responsibilities in the form of job descriptions, which are maintained by the Human Resource department. The responsibility and authority for the quality management system is defined in the following paragraph

#### 5.5.2 Management Representative

The CEO has appointed a Management Representative who, regardless of other responsibilities, has the responsibility for:

- Ensuring that all processes for the quality management system are established, implemented, and maintained
- Reporting to top management on the performance of the quality management system and any needs for improvement
- Ensuring the promotion of customer focus and adherence to customer requirements throughout EMS
- Acting as liaison with external parties on matters relating to EMS quality management system.

#### 5.5.3 Internal Communication

The CEO has identified appropriate communication vehicles and processes (memos, newsletters, meetings, web site, oral communications, e mail, bulletin boards, etc.) to ensure communication takes place regarding the quality management system and its effectiveness.

#### 5.6 Management Review

#### 5.6.1 General

The CEO and the management team review the status of the Company Quality Management System (QMS) to ensure its continuing suitability and effectiveness at planned Management Review meetings.

- 5.6.1.1 The management review identifies opportunities for improvement and any QMS changes needed, review of Quality Objectives and the Quality Policy (annually) for continuing suitability, and reviews resource needs and availability.
- 5.6.1.2 The Management Review activities are recorded. These records include: the minutes, summary results of the internal audits, the main business performance statistics, customer concerns and satisfaction summaries, status/results of contract and design reviews, exception reports on process performance, and reports on the other performance metrics identified as required inputs to the Management Review. The records also include the outputs of the Management Review in the form of Corrective Action initiatives, Preventive Action initiatives, directions for new/different resource allocations, and other actions/requests of the Management Review Team.

Inputs to the Management Review include:

- Summary of Audit results (internal process and system, extrinsic secondparty, third-party, regulatory, etc.) since the last management review.
- Feedback resulting from Customer Communication (complaints, surveys, meeting minutes, customer contacts, etc.)
- Changes that could affect the QMS
- Product Conformity summaries and adverse issues
- Process Performance summaries and adverse issues
- Status of Corrective Actions
- Status of Preventive Actions
- Follow-up actions from previous management reviews
- Other recommendations for improvement

## 5.6.3 Management Review Output

Outputs of the management review are recorded in the meeting minutes and include decisions and actions related to:

- Improving the effectiveness of the QMS and its processes
- Improving the product as related to customer requirements
- Resource needs

#### 5.6.4 Procedure References:

- QMSP 5000 Management Responsibility
- QMSP 4230 Document Control
- QMSP 4240 Control of Records
- QMSP 6220 Competence, Awareness and Training

# 6.0 Resource Management

#### 6.1 Provision of Resources

In actively focusing on the quality management system, EMS regularly reviews resource needs depending on manufacturing workload, strategic direction, and other factors. Top management provides the required resources needed to improve the effectiveness of processes and increase customer acceptance and satisfaction.

#### 6.2 Human Resources

#### 6.2.1 General

EMS encourages the involvement and development of its employees. Personnel performing work affecting conformity to product requirements are competent on the basis of applicable education, training, skills and experience.

## 6.2.2 Competence, awareness and training

All the staff is evaluated and trained in order to be qualified for defined roles. Human Resources oversee and manage the process to:

- Identify and define, using job descriptions, the knowledge and skills needed for all staff performing activities affecting quality.
- Assures necessary training is conducted when required.
- Evaluate the effectiveness of training activities.
- Assure staff awareness of the relevance and importance of their activities and how their involvement contributes to the achievement of the quality objectives.
- Maintains the appropriate records of education, training, skills, and experience of the staff

#### 6.3 Infrastructure

The management and the Management Review Team jointly determine, provide, and maintain a suitable infrastructure as needed to meet all the Quality System and product conformity requirements. This includes attention to: buildings, workspace and associates utilities, process equipment and associated software, and support services such as storage, transport, communication, and information systems.

#### 6.4 Work Environment

The work environment is organised and managed to assure efficient performance of operational activities and conformity to product requirements as well as conform to current laws and Environmental Health and Safety Policies and Procedures.

## 7.0 Product Realization

- 7.1 Planning of Product Realization
- 7.2 Customer Related Processes
  - 7.2.1 Determination of requirements related to products.

Identifying and understanding customer requirements is an essential element of the EMS system. To assure they are correctly and completely recognized and understood, EMS uses a <u>checklist</u> for evaluating the marketing, financial and technical requirements to ensure that:

- The requirements, including those for delivery and after delivery support, are adequately defined and documented;
- Requirements not specified by the customer but known to be necessary are clearly defined;
- All statutory and regulatory requirements applicable to the product are defined;
- EMS has the capability to meet the contract and performance requirements.
- 7.2.2 Review of requirements related to products.

EMS reviews customer requirements per QMSP 7200 Contract Review. This contract review is performed before the commitment to supply the product to the customer (i.e. a proposal, quote, offer, etc.) The review team uses a <a href="https://checklist.com/checklist">checklist</a> for evaluating the marketing, financial and technical requirements to ensure that:

- The requirements are adequately defined and documented;
- Where no written statement is available for an order received by oral means, it shall be ensured that the order requirements are agreed to before their acceptance;
- Any differences between the contract or order requirements and those in the tender are resolved;
- EMS has the capability to meet the contract and performance requirements.

The review team issues a report, provides comments to the check list and details the guidelines for:

- The commercial group solves potential problems or discrepancies with customers
- The project start-up described in the procedures

## Project planning and scheduling

The proposal and contract review records are managed in accordance with QMSP 7200 Contract Review.

#### 7.2.3 Customer communication

Communications during the marketing, sales, proposal and contract definition period shall be managed by Sales Management. Communication during the contract and job execution is managed by the Product manager in charge. In addition Outside Sales Personnel maintain Customer communications. Customer return information, key issues and customer complaint information are fed back to the organization through Sales Trip Reports and through customer complaint management system that is entered in the Everest Quality system. Customer communications requirements are detailed within QMSP7200- Contract Review Procedure and QMSP8210 – Customer Satisfaction Procedure.

## 7.3 Design and Development (as applicable)

#### 7.3.1 Design and development planning

Design activities are identified and planned; qualified personnel are assigned to a crossfunctional design team who are then empowered to bring the product through the New Product Development Process. This team is to generate plans and milestones, including design reviews after each significant step in the process.

Project managers plan, organize, and manage resources, including interfaces between teams and other departments in the organization, as necessary to meet the plan requirements.

Planning output is updated, as appropriate, as the product design and development evolves.

Records of these activities are maintained and, as necessary, distributed.

#### 7.3.2 Design and development inputs

Inputs relating to product requirements are defined and documented. These inputs include functional and performance requirements, applicable regulatory and legal requirements, applicable information derived from previous similar designs, and any other requirements essential for design and development. Engineering reviews these inputs for adequacy. The management team resolves incomplete, ambiguous, or conflicting requirements.

## 7.3.3 Design and development outputs

The outputs of the design and development process are documented by Product Engineering to enable verification against the design and development inputs. Design and development output, assures that we meet the design and development input requirements, provide appropriate information for production and service operations, contain or reference product acceptance criteria, and define the characteristics of the product that are essential to its safe and proper use.

The New Product Development Steering Committee, prior to release to subsequent stages, approves the design and development outputs.

## 7.3.4 Design review

The management team conducts design reviews at planned intervals to assure, the design's ability to meet the customer requirements, the product fits within the business strategy, and to identify design problems and necessary actions early in the process.

#### 7.3.5 Design verification

At appropriate stages of design and development, design verification shall be performed to ensure that the design stage output meets the design stage input requirements. The design verification documents shall be recorded and managed in accordance with the new product development process.

## 7.3.6 Design validation

The design validation of product sold to the customers is normally performed through a series of internal and external tests where all critical product specifications are evaluated internally as well as through Customer Processing and End Product testing.

#### 7.3.7 Control of design changes

Design and development changes and documents produced during the design period are managed by Product Engineering to evaluate the effect of the changes on parts and systems ability to meet their design requirements. Such changes are verified, validated, and approved, where appropriate, before release.

## 7.4 Purchasing

- 7.4.1 EMS has established purchasing processes to ensure purchased product conforms to requirements. EMS
  - a) Evaluates and selects its suppliers based on their ability to supply product in accordance with our requirements;
  - b) Defines the type and extent of control to be exercised depending upon the type of product, the impact of purchased product on the quality of final product, and previously demonstrated capability and performance of suppliers.

The results of evaluations and necessary actions are maintained per QMSP 7400

#### 7.4.2 Purchasing information

Purchasing documents include data describing the products and services, specifications, drawings, and other requirements.

Purchasing documents contain information describing the product to be purchased, including where appropriate:

- a) Requirements for approval of product, procedures, specifications, drawings processes, equipment, and personnel
- b) Quality management system requirements

Purchasing documents are reviewed and approved prior to release to insure that supplied materials, equipment, and services conform to contract, policies and procedures.

## 7.4.3 Verification of purchased product

The verification of purchased product is planned and managed through inspections and testing executed by qualified personnel, according to inspection and test plan defined in the associated Quality procedure or Contract Specification. Certain standard products, standard inspection and testing protocols utilized by suppliers will provide verification.

When necessary, representatives of EMS may arrange for product verification at the supplier's premises. When contractually required, the customer will be authorized access to the supplier's premises for product verification.

## 7.4.3.1 Approved Materials for Ongoing Production

All material used for the manufacturing of product is purchased from approved suppliers only. Additional sources are used only after their addition to the approved suppliers list.

#### 7.4.3.2 Government, Safety, and Environmental Regulations

Materials used in the manufacturing of product satisfy current governmental and safety constraints on restricted, toxic, and hazardous materials; as well as environmental, electrical, and electro-magnetic considerations applicable to the country of manufacture and sale.

## 7.4.3.3 Evaluation of Suppliers

Suppliers are EMS subcontractors. Suppliers are selected on the basis of their documented quality system, performance history, or demonstrated capability to meet specifications.

## 7.4.3.4 Subcontractor Development

Supplier development is performed by assessments of their quality system with a goal of supplier compliance to the ISO9001 Standard. EMS may recognize OEM customer, OEM customer-approved second party and accredited third party audits in place of quality system assessments. Customer-designated suppliers are managed in the same manner as all Key EMS Suppliers.

## 7.4.3.5 Scheduling Suppliers

A system is in place to track Supplier Quality performance and premium freight charges paid by EMS and suppliers on a periodic basis. Corrective actions are taken as appropriate.

#### 7.5 Production and Service Provision

Manufacturing processes are carried out under controlled conditions using documented procedures and suitable equipment in a suitable working environment.

## 7.5.1 Management of Production Activities

EMS controls production provisions under controlled conditions. Controlled conditions include, as appropriate:

- a) The availability of information that describes the key characteristics of the product;
- b) Where necessary, the availability of work instructions, as necessary;
- c) The use of suitable equipment;
- d) The availability and use of monitoring and measuring equipment;
- e) The implementation of monitoring and measurement;
- f) The implementation of product release, delivery and post-delivery activities.
- g) Published standards, laws, codes, and regulations are adhered to, in order to ensure product compliance. Process and equipment approval, and the control and monitoring of critical process parameters by qualified personnel are identified in the operational work instructions and process sheets/route cards.
- Workmanship criteria are defined and documented in Level III work instructions.
   Suitable maintenance on equipment is scheduled to ensure continued process capability.

#### 7.5.2 Validation of processes for production and service provision

EMS validates any production and service processes where the resulting output cannot be verified by subsequent measurement or monitoring, and as a consequence, deficiencies become apparent only after the product is in use or the service has been

delivered. Validation shall demonstrate the ability of these processes to achieve planned results.

EMS has defined arrangements for these processes that include the following, as applicable:

- a) Defined criteria for review and approval of the processes;
- b) Approval of equipment and qualification of personnel;
- c) Use of specific methods and procedures;
- d) Requirements for records and revalidation.

## 7.5.2.1 Automotive Customer Requirements

- a) Premises are maintained in a state of order, cleanliness and repair that is appropriate for the products manufactured.
- b) EMS has contingency plans to reasonably protect our supply of products to our customers in the event of an emergency.
- c) Procedures assure compliance with customer requirements for designation, documentation, and control of special characteristics. Evidence of such compliance is available upon request.
- d) Key process equipment is identified and adequate resources are provided for machine/equipment maintenance and the development of a total preventive maintenance system. As a minimum, this system includes procedures for planned scheduled maintenance activities, predictive maintenance methods, availability of replacement parts, procedures for packaging/preservation of equipment and gages and evaluation and improvement of maintenance objectives.
- e) Special processes requiring qualified operators, monitoring and controls are defined by engineering. Records are maintained for operator, equipment, and process qualification as appropriate.

## 7.5.2.2 Process Monitoring and Operator Instructions

Documented process monitoring and operator instructions, available at work stations, are provided for all employees having responsibility for process operations.

Process monitoring and operator instructions typically take the form of process sheets/route cards, standard operating procedures, and other documents contained in the quality system. As appropriate, these instructions contain operation name and number keyed to a process flow chart, part name and number, current engineering revision/date, required equipment and tooling, material identification, designated special characteristics, SPC requirements, relevant standards, revision level and approval, inspection/test instructions, disposition instructions, corrective action instructions, visual aids, tool change intervals and set-up instructions.

#### 7.5.2.3 Maintaining Process Control

EMS maintains or exceeds process capability and performance requirements for Automotive Customers who approve PPAP submittals. The Control Plan and Process Flow Diagrams are documented and implemented for adherence to measurement techniques, sampling plans, acceptance criteria and reaction plans. Control plan characteristics, which are unstable or non-capable, require initiation of a reaction plan. Typically, reaction plans focus on positive containment and 100% inspection. Corrective action is initiated to return the process to stability and capability. Detailed plans including actions, timing, and responsibility are reviewed and approved by customers when required.

#### 7.5.2.4 Modified Process Control Requirements

When automotive customers define higher or lower capability or performance requirements, Control Plans are annotated accordingly.

#### 7.5.2.5 Verification of Job Setups

Job set-ups are verified prior to producing production quantities. The set-up requirements are documented, available to set-up personnel, and assure part/material conformance to requirements. Statistical methods are used, where applicable.

## 7.5.2.6 Process Changes

A record of process change effective dates is maintained.

## 7.5.2.7 Appearance Items

For customer designated appearance items, appropriate lighting, master standards, maintenance of standards/equipment, and training of employees is provided.

#### 7.5.3 Identification and Traceability

EMS maintains documented procedures for the identification, traceability, and control of material from receipt, through processing and delivery of finished products. For traceability, coil number, lot number and packet/skid number identify material and products processed. EMS establishes and maintains documented procedures for unique identification for individual product or batches, as a specified requirement for traceability. EMS controls and records the unique identification of the product. Traceable to raw material lots. Status is identified with respect to measurement and monitoring requirements per QMSP 7530.

## 7.5.4 Customer Supplied Property and Equipment

Material Management will identify, verify, protect and safeguard customer property provided for use or incorporation into the product, including intellectual property given in confidence. Items that are lost, damaged, or otherwise unsuitable for use are to be recorded and reported to the customer. Verification by EMS does not absolve the customer of the responsibility to provide acceptable product.

## 7.5.4.1 Customer Owned Tooling

Customer owned tools and equipment are permanently marked for visual identification of ownership.

## 7.6 Control of Monitoring and Measuring Equipment

EMS identifies the measurements to be made as well as the monitoring and measurement equipment required to assure product conformity to specified requirements.

Procedures to control the monitoring and measuring equipment's capability are consistent with the monitoring and measuring requirements.

## Requirements:

Monitoring and measuring equipment shall:

- Be calibrated and adjusted periodically or prior to use, against devices traceable to international or national standards; where no such standards exist, the basis used for calibration or verification is recorded;
- Be adjusted or re-adjusted as necessary;
- Be identified to enable calibration status to be determined;
- Be safeguarded from adjustments that would invalidate the measurement result;
- Be protected from damage and deterioration during handling, maintenance and storage;
- Have the results of calibration recorded per procedure QMSP7600

Have the validity of previous results re-assessed if they are subsequently found to be out of calibration, and corrective action taken.

• Have safety criteria for the monitoring and measuring equipment followed

Technical data pertaining to Measuring Equipment is made available to customers for verification when required.

Software used for monitoring and measurement of specified requirements is validated prior to use and reconfirmed as necessary.

## 7.6.1 Measurement System Analysis (MSA, as applicable)

For all measurement Materials and Product referenced in the customer approved control plan, statistical studies are conducted in accordance with the MSA reference manual to analyze possible variation present in the results. Evidence of these studies is maintained.

#### 7.6.2 Calibration Services

Calibration of Inspection Measurement &Test Equipment is conducted externally by qualified organizations or internally by qualified personnel. When calibration is subcontracted to outside sources, it is ensured that they are accredited to or meet the intent of the ISO/EIC Guide 25 or equivalent. Original Equipment Manufacturers are used when an accredited laboratory does not exist.

When calibration is performed in house, documented procedures are used, which require details of the equipment type, unique identification, location, frequency of checks, check methods, acceptance criteria and action to be taken when results are unsatisfactory. Calibration status is identified with a suitable sticker. When the use of a sticker is not practical, other suitable means are used. Calibration records for Measuring Equipment are maintained. When Measuring Equipment is found to be out of calibration, the validity of previous inspection and test results are assessed and documented Calibration, inspection and testing are performed in suitable environmental conditions. Suitable handling, preservation and storage methods are maintained. Measuring Equipment is safeguarded from unauthorized adjustments that would invalidate the calibration setting, where applicable.

#### 7.6.3 Calibration/Verification Records.

Records of calibration/verification activity for all gages/instruments including employee - owned gages that impact product quality include revisions following engineering changes, any out of specification readings as received for calibration, statement of conformance to specification after calibration, and notification to the customer if suspect material may have been shipped.

#### **References Procedures Section 7**

| QMSP-7510              | Control of Production Provisions and Work<br>Instructions | QMSP-7600 | Calibration –Control of Measuring and Monitoring Devices   |
|------------------------|---|-----------|--|
| QMSP-8240              | Inspection and Test                                       | QMSP-7550 | Handling, Storage, Packaging, Preservation and<br>Delivery |
| QMSP-7400<br>QMSP-7530 | Purchasing<br>Identification and Traceability             | •         | Customer Satisfaction Control of Non-conforming Product    |

# 8.0 Measurements, Analysis and Improvement

#### 8.1 General

EMS plans and implements the monitoring, measurement, analysis, and improvement processes needed

- a) to demonstrate conformity to product requirements
- b) to ensure conformity of the quality management system and
- c) to continually improve the effectiveness of the quality management system.

## 8.2 Monitoring and Measurement

#### 8.2.1 Customer satisfaction

EMS monitors information relating to customer perception as to whether we have met customer requirements, as one of the measurements of performance of the quality management system. The methodologies for obtaining and using this information are described in procedure OMSP8210 —Customer Satisfaction

#### 8.2.2 Internal audit

EMS conducts internal audits to determine whether the quality management system conforms to the requirements of ISO 9001:2008 and has been effectively implemented and maintained.

Per QMSP-8220 Internal Auditing Procedure, EMS develops the audit schedule annually, taking into consideration the status and importance of the activity. The audit schedule is revised, if necessary, after each audit and updated. The audit scope, frequency, methods, and criteria are defined. Qualified and trained individuals perform internal Process Audits with no direct responsibility for the areas audited. The Internal Quality Audits are performed monthly with the objective of auditing all the process areas a minimum of once every 18 months.

The results of the audits are recorded and brought to the attention of the personnel and responsible manager in the audited process.

The personnel responsible for the audited process shall take timely corrective actions on deficiencies found during the audit.

Extraordinary Internal Audits can be performed when requested by the customer, in case of significant or major non-conformities or in the situation of considerable Organizational changes.

Follow-up audit activities verify and record the implementation and effectiveness of the corrective actions taken will be part of the continuing Internal Audit Program.

The Internal Audits are recorded in accordance with QMSP 8220- Internal Auditing Procedure and QMSP-4240 Control of Records.

The results of Internal Quality Audits form an integral part of the input to Management Review.

#### 8.2.3 Monitoring and measurement of processes

Quality Management System processes have been identified and are guided in their execution by an integrated information system that allows the monitoring of all the activities and the measurement of chosen performance indicators, including internal audits.

Corrective actions are taken when planned results are not achieved.

## 8.2.4 Monitoring and measurement of product

The monitoring and measurement of products are assured by the Inspection and Test plans as per QMSP 8240 Inspection and Test Procedure and Route Card details. The activities of inspection, acceptance test and release of products are documented and recorded accordingly to include:

- Planned stages for monitoring and measurement
- Evidence of conformance to stated criteria
- Authority responsible for release of product

Product release and service delivery will not proceed until all the specified activities have been satisfactorily completed, unless otherwise approved by a relevant authority or if required, the customer.

## 8.3 Control of Nonconforming Product

EMS applies the process QMSP-8300 Control of Non-Conforming Product to effectively manage the review and disposition of nonconforming product.

#### Particularly

- Ensures that the product not conforming to specified requirements is prevented from unintentional use or installation.
- Provides for identification, documentation, and evaluation of non-conforming product.
- Provides for segregation (when practical) of non-conforming products.
- Controls non-conforming product and notifies the functions affected.

## 8.3.1 Review and disposition of nonconforming products

The responsibilities and authorities for review and disposition of a non-conforming product have been defined and the product may consequently be:

- Re-worked to satisfy the specified requirements
- Accepted as is, by customer authorization and / or concession
- Re-classified for different or less stringent uses
- Scrapped and replaced

When contractually requested, the customer shall be notified regarding the repair and use of non-conforming product, in order to confirm Customer approval. The re-worked product is re-inspected according to the client contract or as specified in QMSP8300

Records are managed per QMSP4240 Control of Records.

Data and statistics concerning non-conformities and eventual non-conformities and poor quality costs are submitted to the Management review.

8.3.2 Prioritized Reduction Plans – Automotive Customers

Nonconforming product is quantified and analyzed as part of a prioritized reduction plan and progress monitored.

#### 8.3.3 Control of Reworked Product

Rework instructions are provided and utilized by appropriate personnel in the work area.

## 8.3.4 Engineering Approved Product Authorization

Customer authorization is obtained whenever the product or process varies from the one currently approved. This requirement also applies to products purchased from suppliers. EMS evaluates supplier requests prior to submission to the customer for authorization. A record of the expiration date or quantity authorized is maintained. Procedures ensure compliance with original or superseding specifications when the authorization expires. Material shipped on an authorization is clearly marked on each shipping container.

#### 8.4 Analysis of Data

EMS determines, collects and analyzes appropriate data to determine the suitability and effectiveness of the quality management system and to identify improvements that can be made. This includes data generated by monitoring and measurement activities and other relevant sources.

EMS analyzes this data to provide information on:

- Customer satisfaction and/or dissatisfaction
- Product conformity and nonconformity to requirements
- Performance trends and opportunity for improvements of the Company processes, including preventive actions
- Performance of suppliers

#### 8.5 Improvement

#### 8.5.1 Continual Improvement

EMS assures the improvement of Company performance by checking the status of achievement against established targets of the Quality Management System.

This includes the use of quality policy, quality objectives, audit results, analysis of data, corrective actions, preventive actions, and management review using procedures QMSP8523 Corrective and Preventive Action and QMSP8600 Continuous Improvement.

#### 8.5.2 Corrective Action

EMS takes corrective action to avoid and eliminate the cause of nonconformities in order to prevent recurrence. Corrective action is to be appropriate to the impact of the nonconformities encountered. The documented procedure for corrective actions QMSP8523 includes:

- a) The effective handling of customer complaints and reports of product nonconformities
- b) Investigation of the cause of non-conformities relating to product, process and quality system, and recording the results of investigation
- c) Determination of corrective action needed to eliminate the causes of nonconformities
- d) Application of controls to ensure the corrective action is taken and those actions taken are effective.

#### 8.5.3 Preventive Action

EMS identifies preventive action to avoid and eliminate the causes of potential nonconformities to prevent occurrence. Preventive actions taken are appropriate to the impact of the potential problems. The documented procedure for preventive action, QMSP8523, defines requirements for:

- a) Determining potential nonconformities and their causes
- b) Evaluating the need for action to prevent occurrence of nonconformities
- c) Determining and implementing action needed
- d) Recording results of action taken
- e) Reviewing of preventive action taken

## 8.5.3.1 Problem Solving Methods

A disciplined problem solving methodology is used when internal or external non-conformances occur. When required, responses are made in the manner prescribed by the customer.

#### 8.5.3.2 Mistake Proofing

Mistake proofing methodology is used where appropriate.

## 8.5.3.3 Returned Product Test/Analysis

Parts returned from customers are analyzed, and records of these analyses are made available upon request. The appropriate corrective actions are implemented to prevent recurrence.

## 8.5.3.4 Corrective Action Impact

Corrective actions taken and controls implemented to eliminate the cause of nonconformity are also applied to similar processes and products where appropriate.