ISO 9001:2008
QUALITY MANAGEMENT SYSTEM

GH METAL SOLUTIONS, INC.

Quality Manual
<table>
<thead>
<tr>
<th>Issue Date</th>
<th>Change Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>04/21/06</td>
<td>INITIAL RELEASE</td>
</tr>
<tr>
<td>01/10/07</td>
<td>UPDATE QUALITY OBJECTIVES</td>
</tr>
<tr>
<td>9/18/08</td>
<td>REWORKED TO COMPLY WITH GH METHODS</td>
</tr>
<tr>
<td>08/04/09</td>
<td>CHANGED TO 9001:2008</td>
</tr>
<tr>
<td>09/25/09</td>
<td>CHANGED SCOPE, JUSTIFIED EXCLUSION OF DESIGN</td>
</tr>
<tr>
<td>02/01/11</td>
<td>CHANGED NAME OF COMPANY TO GH METAL SOLUTIONS AND UPDATED THE APPROVAL NAMES</td>
</tr>
<tr>
<td>01/20/12</td>
<td>CHANGED PROCESS CHART (PAGE 9)</td>
</tr>
</tbody>
</table>
# Table of Contents

<table>
<thead>
<tr>
<th>Section</th>
<th>Title</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.0</td>
<td>Scope</td>
<td>4</td>
</tr>
<tr>
<td>1.1</td>
<td>General</td>
<td>4</td>
</tr>
<tr>
<td>1.2</td>
<td>Application</td>
<td>4</td>
</tr>
<tr>
<td>1.3</td>
<td>Exclusions / Exceptions</td>
<td>4</td>
</tr>
<tr>
<td>1.4</td>
<td>Quality Policy Statement</td>
<td>5</td>
</tr>
<tr>
<td>1.5</td>
<td>Objectives for Quality</td>
<td>5</td>
</tr>
<tr>
<td>1.6</td>
<td>Management Commitment and Approval</td>
<td>6</td>
</tr>
<tr>
<td>2.0</td>
<td>Quality Management System Structure</td>
<td>7</td>
</tr>
<tr>
<td>2.1</td>
<td>Matrix to Quality System Requirements</td>
<td>8</td>
</tr>
<tr>
<td>2.2</td>
<td>GH Metal Solutions Process Model</td>
<td>9</td>
</tr>
<tr>
<td>2.3</td>
<td>Nonapplicable Requirements</td>
<td>10</td>
</tr>
<tr>
<td>3.0</td>
<td>Company Profile</td>
<td>10</td>
</tr>
<tr>
<td>3.1</td>
<td>Organizational Chart</td>
<td>11</td>
</tr>
<tr>
<td>4.0</td>
<td>Quality Management System</td>
<td>12</td>
</tr>
<tr>
<td>4.1</td>
<td>General Requirements</td>
<td>12</td>
</tr>
<tr>
<td>4.2</td>
<td>Documentation Requirements</td>
<td>11</td>
</tr>
<tr>
<td>4.2.1</td>
<td>General</td>
<td>11</td>
</tr>
<tr>
<td>4.2.2</td>
<td>Quality Manual</td>
<td>11</td>
</tr>
<tr>
<td>4.2.3</td>
<td>Control of documents</td>
<td>11</td>
</tr>
<tr>
<td>4.2.4</td>
<td>Control of records</td>
<td>12</td>
</tr>
<tr>
<td>5.0</td>
<td>Management responsibility</td>
<td>12</td>
</tr>
<tr>
<td>5.1</td>
<td>Management commitment</td>
<td>12</td>
</tr>
<tr>
<td>5.2</td>
<td>Customer focus</td>
<td>12</td>
</tr>
<tr>
<td>5.3</td>
<td>Quality policy</td>
<td>13</td>
</tr>
<tr>
<td>5.4</td>
<td>Planning</td>
<td>13</td>
</tr>
<tr>
<td>5.4.1</td>
<td>Quality objectives</td>
<td>13</td>
</tr>
<tr>
<td>5.4.2</td>
<td>Quality Management system planning</td>
<td>14</td>
</tr>
<tr>
<td>5.5</td>
<td>Responsibility, authority, and communication</td>
<td>13</td>
</tr>
<tr>
<td>5.5.1</td>
<td>Responsibility and authority</td>
<td>13</td>
</tr>
<tr>
<td>5.5.2</td>
<td>Management Representative</td>
<td>13</td>
</tr>
<tr>
<td>5.5.3</td>
<td>Internal communication</td>
<td>13</td>
</tr>
<tr>
<td>5.6</td>
<td>Management Review</td>
<td>15</td>
</tr>
<tr>
<td>5.6.1</td>
<td>General</td>
<td>15</td>
</tr>
<tr>
<td>5.6.2</td>
<td>Review input</td>
<td>14</td>
</tr>
<tr>
<td>5.6.3</td>
<td>Review output</td>
<td>14</td>
</tr>
<tr>
<td>6.0</td>
<td>Resource Management</td>
<td>14</td>
</tr>
<tr>
<td>6.1</td>
<td>Provision of resources</td>
<td>14</td>
</tr>
<tr>
<td>6.2</td>
<td>Human resources</td>
<td>14</td>
</tr>
<tr>
<td>6.2.1</td>
<td>General</td>
<td>14</td>
</tr>
<tr>
<td>6.2.2</td>
<td>Competence, awareness and training</td>
<td>14</td>
</tr>
<tr>
<td>6.3</td>
<td>Infrastructure</td>
<td>15</td>
</tr>
<tr>
<td>6.4</td>
<td>Work environment</td>
<td>15</td>
</tr>
<tr>
<td>7.0</td>
<td>Product realization</td>
<td>15</td>
</tr>
<tr>
<td>7.1</td>
<td>Planning of product realization</td>
<td>15</td>
</tr>
<tr>
<td>7.2</td>
<td>Customer-related processes</td>
<td>15</td>
</tr>
<tr>
<td>7.2.1</td>
<td>Determination of requirements related to the product</td>
<td>15</td>
</tr>
<tr>
<td>7.2.2</td>
<td>Review of requirements related to the product</td>
<td>16</td>
</tr>
<tr>
<td>7.2.3</td>
<td>Customer communication</td>
<td>16</td>
</tr>
<tr>
<td>7.3</td>
<td>General</td>
<td>18</td>
</tr>
<tr>
<td>7.4</td>
<td>Purchasing</td>
<td>16</td>
</tr>
<tr>
<td>7.4.1</td>
<td>Purchasing process</td>
<td>16</td>
</tr>
<tr>
<td>7.4.2</td>
<td>Purchasing information</td>
<td>16</td>
</tr>
</tbody>
</table>
7.4.3 Verification of purchased product
7.5 Production and service provision
7.5.1 Control of production and service provision
7.5.2 Validation of Processes for Production and Service Provision
7.5.3 Identification and traceability
7.5.4 Customer property
7.5.5 Preservation of product
7.6 Control of monitoring and measuring devices
8 Measurement, analysis and improvement
8.1 General
8.2 Monitoring and measurement
8.2.1 Customer satisfaction
8.2.2 Internal audit
8.2.3 Monitoring and measurement of processes
8.2.4 Monitoring and measurement of product
8.3 Control of nonconforming product
8.4 Analysis of data
8.5 Improvement
8.5.1 Continual improvement
8.5.2 Corrective action
8.5.3 Preventive action
1.0 Scope.

The Manufacture, Fabricating and Coating of Parts and Assemblies for Various Industries.

GH Metal Solutions was founded in 1958, when natural gas was first made available to Ft. Payne and began as a Heating and Air-conditioning Sales and Service Company. From the beginning GH Metal Solutions has been locally owned and operated and continues in this fashion today. In 1982, the company phased out heating and air-conditioning operations to concentrate solely on manufacturing and fabrication of metal parts. GH Metal Solutions has become a major supplier of both components and weldments to the agricultural, material handling, and transportation industries. GH Metal Solutions uses a wide variety of lasers, shears, press brakes, punch presses, saws, machining equipment, welders, and other metal processing equipment. We are committed to maintaining high quality standards while providing these services at a competitive price.

This quality manual and its related documents make up the quality policies and procedures of GH Metal Solutions, Inc. Each employee is required to do their job as written in the quality policy and related procedures.

1.1 General.

GH Metal Solutions’ Quality Management System (QMS) is the means of implementing process improvements and ensuring all products and services conform to specified customer and company requirements.

1.2 Application.

GH Metal Solutions Quality Manual documents the systematic requirements and principles for its QMS. It governs policies, Standard Operational Procedures and Work Instructions and specifies how they relate to the overall operation of the QMS. It is consistent with the Business’s Vision, Values and Quality Policy. It assigns responsibilities and sets up authority for carrying out quality processes to consistently meet our customer’s contractual requirements and quality expectations.

The QMS requirements also apply to efforts in servicing of deliverable product/s.

1.3 Exceptions / Exclusions.

Requirements of 7.3, Design & Development requirements are excluded from GH Metal Solutions QMS.

Justification: GH Metal Solutions is not responsible for design of products as defined in scope. GH Metal Solutions works to the customer requirements only.

1.4 Quality Policy Statement

It is the policy of GH Metal Solutions to provide products, services and customer support of the highest
quality in the respective market segments served. In all activities, GH Metal Solutions’ Quality Policy is:

“Quality and Continual Improvement are our basic operating principles. These principles will be met by understanding the requirements of our Customers and consistently meeting or exceeding those requirements”.

1.5 Objectives for Quality

- The management at GH Metal Solutions has implemented a quality system as a means of achieving the following Quality goals: GH Metal Solutions’ Management has formally endorsed and established Quality objectives. These are defined in GH-CL-5.4-2, GH Metal Solutions Quality Plan.

GH Metal Solutions communicates quality objectives to all employees through training, meetings, newsletters, and other means. Progress toward achieving these objectives is tracked and regularly publicized to employees.

To help meet these objectives, GH Metal Solutions is pursuing a plan to implement, maintain, and obtain registration for a quality management system that meets the requirements of:

ISO 9001:2008
Quality Management Systems - Requirements
1.6 Management Commitment and Approval.

**Commitment**

GH Metal Solutions management and employees are committed to our Quality Policy. Everyone understands their role in the QMS and works within it to help achieve our quality objectives. Management regularly reviews the performance of the quality system to assess, assure, and improve its effectiveness.

**Approval**

This Quality Manual has been reviewed and approved on the date entered on the Document Approval/Change History Record.

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<thead>
<tr>
<th>Name</th>
<th>Name</th>
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</tr>
</thead>
<tbody>
<tr>
<td>BRAD SCOTT</td>
<td>Alan Kilgo</td>
<td>Edwin Stanley</td>
</tr>
<tr>
<td>V.P. – Engineering &amp; Services</td>
<td>V.P. – Operations</td>
<td>V.P. – Sales &amp; Finance</td>
</tr>
</tbody>
</table>
2.0 Quality Management System Structure.

GH Metal Solutions’ QMS consists of the following elements:

**Quality Manual** - Defines GH Metal Solutions’ quality policies and fully defines quality practices (including responsibility and authority) for activities and cross-references to Procedures (Ref. Section 2.1).

**Procedures** - Required by the International Standard or by GH Metal Solutions define quality processes (including responsibility and authority). They also cross-reference to Work Instructions (where relevant).

**Work Instructions** - required by GH Metal Solutions for certain quality-intensive tasks.

**Records, Forms and Related Documents** – are as specified by Procedures or Work Instructions, as appropriate.

**Master List** – Required by the International Standard or by GH Metal Solutions to verify the latest revision level of a given document.

**Documentation Hierarchy**

The QMS requirements apply to all GH Metal Solutions efforts engaged in servicing of deliverable products and services.

This Manual describes quality responsibilities and policies consistent with International Standard, *ISO 9001:2008 Quality Management Systems - Requirements*. When required, program specific quality plans add to the requirements of this Manual to meet specific contract requirements.

GH Metal Solutions maintains procedures consistent with requirements of this Manual for control of quality processes.

GH Metal Solutions Audit Team is responsible for maintaining an independent audit function to monitor the adherence to the requirements of this Manual and implementing of procedures. Audits verify that the organization is following the procedures and work instructions. It also demonstrates the process for maintaining the QMS and its effectiveness.

This Manual is reviewed by GH Metal Solutions annually and updated as needed. The procedures and work instructions are reviewed and updated per document change procedure requirements GH-SOP-4.2.
GH Metal Solutions Quality Manual, QMS Procedures and Work Instructions are maintained on GH Metal Solutions Network Drive under the QMS Section. These documents are the most current set of QMS documents. All printed copies except the master set are considered to be uncontrolled.

Note: Responsibility and authority is defined in Quality System Procedures; for processes not defined by procedures, responsibility and authority is defined in the relevant section of this Quality Manual. GH Metal Solutions Quality Manual is structured under the ISO 9001:2008 Quality Management Systems – Requirements.
Non-Applicable Requirements


All Requirements except section 7.3 have been met in GH Metal Solutions Quality Manual, Procedures and Work Instructions

3.0 Company Profile

GH Metal Solutions is in the business of providing quality manufactured parts and assemblies to satisfy requirements of its customers around the world.

- GH Metal Solutions conducts its business legally and ethically, with a major objective of meeting customer needs and contractual requirements on time and within agreed costs.
- GH Metal Solutions operates its business competitively and with dedication to the professional well being of our employees and with support to our local communities.

GH Metal Solutions has identified four Values, which support strategies of our business and are critical to achieving long-term success and Vision. They are enduring and are meant to guide employees in their daily work. They are also based upon GH Metal Solutions’ dedication to customers, employees, shareholder expectations, high ethical standards and social responsibilities.

Teamwork - The road to success starts with a team-minded approach. Effective teamwork among employees and with customers is the foundation upon which solid, total customer solutions are built. GH Metal Solutions uses the expertise of its professionals/employees to work as a single unit to efficiently deliver services, solve problems, improve processes and provide added value.

Trust – GH Metal Solutions builds relationships on trust with our customers and employees. We’ve proven that trusting relationships produce sound business practices.

Empowerment – GH Metal Solutions relies on the front-line support of key people to keep us a step ahead. We delegate responsibility and authority to employees who are closest to the job at hand. We stimulate and encourage initiative in each other to search for new, unique ideas and to maintain an environment of continual learning.

Commitment to People - Our vision is firmly entrenched in the results we produce for the people we serve.

3.1 GH METAL SOLUTIONS ORGANIZATIONAL CHART

See GH-QP-5.1-1 Organizational Chart for current structure.
4.0 Quality Management System.

4.1 General Requirements

GH Metal Solutions has established, documented, and implemented a Quality Management System (QMS) in accordance with the requirements of the International Standard ISO 9001:2008. The company maintains and continually improves the effectiveness of its QMS. GH Metal Solutions:

a) Has identified the processes needed for the QMS and their application throughout the organization.
b) Has determined the sequence and interaction of these processes.
c) Has determined criteria and methods needed to ensure that both the operation and control of these processes are effective.
d) Ensures the availability of resources and information necessary to support the operation and monitoring of these processes.
e) Monitors, measures and analyzes these processes.
f) Implements actions necessary to achieve planned results and continual improvement of these processes.

These processes are managed by GH Metal Solutions in accordance with the requirements of International Standard referenced above. GH Metal Solutions insures outsourced processes are monitored in accordance to product quality and customer requirements.

4.2 Documentation Requirements

4.2.1 General

The Management Representative has overall responsibility and authority for QMS documentation (with the exception of records, which are addressed in a written procedure – Ref. GH-SOP-4.2. The QMS documentation includes:

a) Documented statements of a quality policy and quality objectives.
b) A quality manual.
c) Documented procedures required by International Standard as referenced above,
d) Documents needed by GH Metal Solutions to ensure the effective planning, operation and control of its processes.
e) Records required by the International Standard.

4.2.2 Quality Manual

GH Metal Solutions has established and maintains this quality manual. The Management Representative has the responsibility and authority for development, approval, issue, and revision of the Manual. It includes the scope of the QMS, including details of and justification for exclusions (Section 2.2) and a description of the interaction among the processes of the QMS (Section 2.1).

4.2.3 Control of Documents

Documents required by the QMS are controlled. Records are a special type of document and are controlled according to the requirements given in GH-SOP-4.2.
A documented procedure is established to define the controls needed to:

a) Approve documents for adequacy prior to issue.
b) Review and update as necessary and re-approve documents.
c) Ensure that changes and the current revision status of documents are identified.
d) Ensure that relevant versions of applicable documents are available at points of use.
e) Ensure that documents remain legible and readily identifiable.
f) Ensure that documents of external origin are identified and their distribution controlled.
g) Prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.

4.2.4 Control of Records

Records are established and maintained to provide evidence of conformity to requirements and of the effective operation of the QMS. Records remain legible, readily identifiable and retrievable. A documented procedure (Ref. GH-SOP-4.2) is established to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of records.

5.0 Management Responsibility.

5.1 Management Commitment

Senior management at GH Metal Solutions is ultimately responsible for the quality of products provided, as well as the implementation of the Quality Management System. Management personnel routinely demonstrate their commitment to the development and implementation of the Quality Management System and continually improving its effectiveness by:

a. Communicating to the company the importance of meeting customer as well as statutory and regulatory requirements. (Reference Section 5.5.3)
b. Establishing the Quality Policy. (Reference Section 5.3)
c. Ensuring that Quality Objectives are established. (Reference Section 5.4.1)
d. Conducting Management Reviews. (Reference Section 5.6)
e. Ensuring the availability of resources. (Reference Section 6.1)

5.2 Customer Focus

Management ensures that customer requirements are determined and are met with the aim of enhancing customer satisfaction
5.3 Quality Policy

GH Metal Solutions Management ensures that the quality policy:

a) Is appropriate to the purpose of GH Metal Solutions.
b) Includes a commitment to comply with requirements and continually improve the effectiveness of the QMS.
c) Provides a framework for establishing and reviewing quality objectives.
d) Is communicated and understood within GH Metal Solutions.
e) Is reviewed for continuing suitability.

5.4 Planning

a)

5.4.1 Quality Objectives

Management ensures that quality objectives, including those needed to meet requirements for Service are established at relevant functions and levels within GH Metal Solutions. The quality objectives are measurable and consistent with the quality policy.

5.4.2 Quality Management System Planning

Management ensures that planning of the QMS is carried out in order to meet the requirements in Section 4.1 as well as its Quality Objectives. The integrity of the QMS is maintained when changes to the QMS are planned and implemented.

5.5 Responsibility, Authority, and Communication.

5.5.1 Responsibility and Authority

GH Metal Solutions Management ensures that responsibilities and authorities are defined and communicated within GH Metal Solutions. This is done via this Quality Manual or relevant Procedures. See Organizational Chart GH-QP-5.1-1.

5.5.2 Management Representative

The Executive Management at GH Metal Solutions has appointed a member of Management who, irrespective of other responsibilities, has responsibilities and authority that includes ensuring that processes needed for the QMS are established, implemented and maintained, reporting to Management on the performance of the QMS and any need for improvement, and ensuring the promotion of awareness of customer requirements throughout the organization.

5.5.3 Internal Communication

Management ensures that appropriate communication processes are established within GH Metal Solutions and that communication takes place regarding the effectiveness of the QMS.
5.6 Management Review
The Management Review process is defined in GH-SOP-5.6.

5.6.1 General

Management reviews GH Metal Solutions’ QMS, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness. This review includes assessing opportunities for improvement and the need for changes to the QMS, including the quality policy and quality objectives.

Records from Management Reviews are maintained.

5.6.2 Review Input

The Management Representative ensures that input to Management review includes information on:

a) Results of audits.
b) Customer feedback.
c) Process performance and product conformity.
d) Status of preventive and corrective actions.
e) Follow-up actions from previous Management reviews.
f) Changes that could affect the QMS.
g) Recommendations for improvement.

5.6.3 Review Output

The output from the Management review includes any decisions and actions related to:

a) Improvement of the effectiveness of the QMS and its processes.
b) Improvement of product related to customer requirements.

Resource needs

6.0 Resource Management.

6.1 Provision of Resources

GH Metal Solutions managers and supervisors determine and provide resources needed to implement, maintain and continually improve the effectiveness of the QMS. Resources needed to enhance and meet customer requirements and satisfaction is also identified and provided.

6.2 Human Resources

6.2.1 General

GH Metal Solutions employees performing work affecting product/service quality are competent on the basis of appropriate education, training, skills and experience.

6.2.2 Competence, Awareness and Training

GH Metal Solutions:

a) Determines the necessary competence for employees performing work affecting service quality.
b) Provides training or take other action to satisfy these needs.
c) Evaluates the effectiveness of the actions taken.
d) Ensures that its employees are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives.
e) Maintains appropriate records of education, training, skills and experience

6.3 Infrastructure

GH Metal Solutions determines, provides and maintains the infrastructure needed to achieve conformity to product and service requirements. Infrastructure includes, as applicable buildings, workspace and associated utilities, process equipment (both hardware and software) and supporting services (such as transport or communication).

6.4 Work Environment

GH Metal Solutions Management has determined, and manages via defined processes, the work environment needed to achieve conformity to product requirements. GH Metal Solutions’ processes are such that no special measures are required to achieve or maintain work environment adequate to meet customer requirements. Work environment problems affecting service conformity are reported and dealt with via corrective or preventive action procedures.

7.0 Product Realization.

7.1 Planning of Product Realization

GH Metal Solutions plans and develops the processes needed for product/service realization. Planning of product or service realization is consistent with the requirements of the other processes of the QMS.

In planning product realization, GH Metal Solutions determines the following, as appropriate:

a) Quality objectives and requirements for the product or service.
b) The need to establish processes, documents, and provide resources specific to the product.
c) Required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptance.
d) Records needed to provide evidence that the realization processes and resulting service meet requirements.

The output of this planning is in a form suitable for GH Metal Solutions methods of operation.

7.2 Customer-related Processes

7.2.1 Determination of Requirements Related to the Product

GH Metal Solutions determines:

a) Requirements specified by the customer, including the requirements for delivery and post-delivery activities.
b) Requirements not stated by the customer but necessary for specified or intended use, where known.
c) Statutory and regulatory requirements related to the product or service.
d) Any additional requirements determined by the organization.

7.2.2 Review of Requirements Related to the Product

GH Metal Solutions reviews the requirements related to its products. This review is conducted prior to GH Metal Solutions’ commitment to supply a product to the customer (e.g. submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders) and ensures that product requirements are defined, contract or order requirements differing from those previously expressed are resolved, and GH Metal Solutions has the ability to meet the defined requirements. Records of the results of the review and actions arising from the review are maintained.

Where the customer provides no documented statement of requirement, the customer requirements are confirmed by GH Metal Solutions before acceptance. Note: GH Metal Solutions, Inc. reserves the right to use hand sketches, notes or any other customer supplied documentation as a means of control for production of product/service.

Where product requirements are changed, GH Metal Solutions ensures that relevant documents are amended and that the relevant employees are made aware of the changed requirements.

7.2.3 Customer Communication

GH Metal Solutions determines and implements effective arrangements for communicating with customers in relation to product information, inquiries, contracts or order handling, including amendments, customer feedback and complaints.

Clear communication channels have been established with the customer to ensure that orders and changes to orders are placed and fulfilled in a controlled manner. Customer complaints and compliments are communicated to GH Metal Solutions by the Sales, Customer Service, or Customer Technical personnel. This is done to ensure that long term corrective action is taken, where appropriate, to prevent recurrence of any problems.

7.4 Purchasing

7.4.1 Purchasing Process

GH Metal Solutions ensures that purchased product conforms to specified purchase requirements. The type and extent of control applied to the supplier and the purchased product is dependent upon the effect of the purchased product on subsequent product/service realization or the final product or service.

GH Metal Solutions evaluates and selects suppliers based on their ability to supply product in accordance with GH Metal Solutions’ requirements. The Criteria for selection, evaluation and re-evaluation are established. Records of the results of evaluations and any necessary actions arising from the evaluation are maintained.

7.4.2 Purchasing Information

Purchasing information describes the product to be purchased, including where appropriate
requirements for approval of product, procedures, processes and equipment, requirements for qualification of employees, and QMS requirements.

GH Metal Solutions ensures adequacy of specified purchase requirements prior to their communication to the supplier.

7.4.3 Verification of Purchased Product

GH Metal Solutions has established and implemented inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements.

Where GH Metal Solutions or its customer intends to perform verification at the supplier's premises, GH Metal Solutions states the intended verification arrangements and method of product release in the purchasing information.

7.5 Control of Production and Service Provision

7.5.1 Control of Production and Service Provision

GH Metal Solutions plans and carries out production and service provisions under controlled conditions. Controlled conditions include, as applicable:

a) Availability of information that describes the characteristics of the product or service.
b) Availability of work instructions, as necessary.
c) Use of suitable equipment.
d) Availability and use of monitoring and measuring devices.
e) Implementation of monitoring and measurement.
f) Implementation of release, delivery and post-delivery activities.

GH Metal Solutions, Inc. has a specific business need to have the ability to process limited customized Orders where respective part drawings are pre-approved by the customer. Given cost considerations all order processing requirements associated with these Orders are thereby waived. All other Drawings and associated records of such transactions are kept as records.

7.5.2 Validation of Processes for Production and Service Provision.

7.5.2.1 Performance and Verification of Servicing.

Quality system activities related to servicing operations are similar to the corresponding activities related to manufacturing, and delivery of customer’s products. All relevant procedures established for production operations equally apply to servicing. Work instructions issued by the Customer Service supplement those procedures.

7.5.3 Identification and Traceability

Where appropriate, GH Metal Solutions identifies its products by suitable means throughout service realization. GH Metal Solutions identifies the product status with respect to monitoring and measurement requirements. Where traceability is a requirement, GH Metal Solutions controls and records the unique
identification of the product.

7.5.4 Customer Property

GH Metal Solutions exercises care with customer property while it is under its control or use. GH Metal Solutions identifies, verifies, protects and safeguards customer property for use or incorporation into its product. If any customer property is lost, damaged or otherwise found to be unsuitable for use, it is reported to the customer and records maintained.

7.5.5 Preservation of Product

GH Metal Solutions preserves conformity of product during internal processing and delivery to intended destination. Preservation includes identification, handling, packaging, storage and protection. Preservation also applies to the preservation requirements of constituent parts of a product.

7.6 Control of Monitoring and Measuring Devices

GH Metal Solutions determines the monitoring and measurement to be undertaken and the monitoring and measuring devices needed to provide evidence of conformity of product to determined requirements.

GH Metal Solutions has established processes to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements.

Where necessary to ensure valid results, measuring equipment is:

a) Calibrated or verified at specified intervals, or prior to use, against measurement standard traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification is recorded.

b) Adjusted or re-adjusted as necessary.

c) Identified to enable the calibration status to be determined.

d) Safeguarded from adjustments that would invalidate the measurement result.

e) Protected from damage and deterioration during handling, maintenance and storage.

In addition, GH Metal Solutions assesses and records the validity of the previous measuring results when the equipment is found not to conform to requirements. GH Metal Solutions takes appropriate action on the equipment and any product affected. Records of the results of calibration and verification are maintained.

When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application is confirmed. This is undertaken prior to initial use and reconfirmed as necessary.

8.0 Measurement, Analysis and Improvement.

8.1 General

GH Metal Solutions plans and implements the monitoring, measurement, analysis and improvement
processes needed to demonstrate conformity of the product and or service, to ensure conformity of the QMS, and to continually improve its effectiveness. This includes determination of applicable methods, including statistical techniques as appropriate, and the extent of their use.

### 8.2 Monitoring and Measurement

#### 8.2.1 Customer Satisfaction

As one of the measurements of the performance of the QMS, GH Metal Solutions monitors information relating to customer perception as to whether it has met customer requirements. Methods for obtaining and using this information are established.

#### 8.2.2 Internal Audit

GH Metal Solutions conducts internal audits at planned intervals to determine whether the QMS conforms to planned arrangements, to the requirements of the International Standard and QMS requirements established by GH Metal Solutions is effectively implemented and maintained.

An audit program is planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency and methods are defined. Selection of auditors for conducting audits ensures objectivity and impartiality of the audit process. Auditors do not audit their own work.

The responsibilities and requirements for planning, conducting, reporting results and maintaining records are defined in a documented procedure.

The Management responsible for the area being audited ensures that actions are taken without undue delay to eliminate detected nonconformities and their causes. Follow-up activities include the verification of the actions taken and the reporting of verification results.

#### 8.2.3 Monitoring and Measurement of Processes

GH Metal Solutions applies suitable methods for monitoring and, where applicable, measurement of the QMS processes. These methods demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, corrective action are taken, as appropriate, to ensure conformity of the product and or service.

#### 8.2.4 Monitoring and Measurement of Product

GH Metal Solutions monitors and measures the characteristics of its product to verify that product requirements have been met. This is carried out at appropriate stages of the product/service realization process in accordance with the planned arrangements.

Evidence of conformity with the acceptance criteria is maintained. Records indicate the person(s) authorizing release of product.

Product release and service delivery do not proceed until all planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority, and, where applicable, by the customer.
8.3 Control of Nonconforming Product.

GH Metal Solutions ensures that products that do not conform to product requirements are identified and controlled to prevent unintended use or delivery. The controls and related responsibilities and authorities for dealing with nonconforming product are defined in a documented procedure.

GH Metal Solutions deals with nonconforming product by one or more of the following ways: by taking action to eliminate the detected nonconformity; by authorizing its use, release or acceptance under concession by a relevant authority and, where applicable, by the customer; by taking action to preclude its original intended use or application. Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, are kept.

When nonconforming product is corrected at GH Metal Solutions, it is subject to re-verification to demonstrate conformity to requirements.

When nonconforming product is detected after delivery or use has started, GH Metal Solutions takes action appropriate to the effects, or potential effects, of the nonconformity.

8.4 Analysis of Data

GH Metal Solutions determines, collects and analyzes appropriate data to demonstrate the suitability and effectiveness of the QMS and to evaluate where continual improvement of the effectiveness of the QMS can be made. This includes data generated as a result of monitoring and measurement and from other relevant sources.

The analysis of data provides information relating to customer satisfaction, conformance to product requirements, characteristics and trends of processes and products including opportunities for preventive action, and suppliers.

8.5 Improvement

8.5.1 Continual Improvement

GH Metal Solutions continually improves the effectiveness of the QMS through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and Management review.

8.5.2 Corrective Action

GH Metal Solutions takes action to eliminate the cause of nonconformities in order to prevent recurrence. Corrective actions are appropriate to the effects of the nonconformities encountered.

A documented procedure is established to define requirements for:

a) Reviewing nonconformities (including customer complaints).
b) Determining the causes of nonconformities.
c) Evaluating the need for action to ensure that nonconformities do not recur.
d) Determining and implementing action needed.
e) Records of the results of action taken.
f) Reviewing corrective action taken.
8.5.3 Preventive Action

GH Metal Solutions determines action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions are appropriate to the effects of the potential problems.

A documented procedure is established to define 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) Records of results of action taken.
   Reviewing preventive action taken