Acro METALCRAFT Solutions 325 MORGAN AVE • AKRON OHIO • 44311		Acro/Metalcraft Solutions Operating Procedure
Document ID: QM01	Rev. 07	Title: Quality Manual
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 AKRON OHIO 
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**Quality Manual** 

#### The Manufacture of Forming Tools and Stamped and Machined Components

The Quality Management System is designed to meet the requirements of

ISO 9001: 2015 Acro Certificate Number: 10415 ISO 13485: 2016 Acro Certificate Number: 130663

ISO 9001: 2015 Metalcraft Solutions Certificate Number: 051320 ISO 13485: 2016 Metalcraft Solutions Certificate Number: 051320

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# **Amendments**

All copies of this Quality Manual must be kept under strict control to prevent the system from becoming unreliable. The following Procedures will ensure that the system remains current and valid.

- 1) All copies of the manual are to be clearly numbered.
- 2) The Quality Manager /Quality Representative is to be responsible for all revisions and additions being recorded.
- 3) Changes can be suggested by any Employee but must receive signed approval before being entered into the Manual.
- 4) All changes are to be recorded on the Table of Amendment and appropriate pages in each Manual changed.
- 5) Once printed the Manual and all other processes, work instructions and forms are no longer controlled and it is clearly displayed on the bottom of each page.





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Table of Amendment – Quality Manual					nual
Document Number	Page Number	Issue	Date	Description of Change	Authorization
All	All	1	1/6/09	Complete re-issue in compliance with ISO 9001:2008	MARK ALLEN WEIGAND 1/6/09
All	All	2	11/14/11	Changed Authorization from Mark Allen Weigand to Terry Ellis	TERRY ELLIS 11/14/11
QM6	8	3	9/12/13	Quality Objectives ISO 13485: 2012	TERRY ELLIS 01/05/17
QM6	8	4	1/15/18	Quality Objectives ISO 9001:2015	TERRY ELLIS 01/04/18
QM06 QM07	8 10 -11	5	12/27/18 1/8/19	Quality Objectives Organization	Terry Ellis 03/14/10
All	All	6	09/14/20	Added Metalcraft Solutions ISO 13485:2016	Terry Ellis 09/14/20
All	All	7	10/07/2021	Changed format, added auditors, eliminated copy holder, distribution pages	Eric Patterson 10/07/2021

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# **Company Profile**

ACRO TOOL & DIE COMPANY, INC./METALCRAFT SOLUTIONS, (The Company) was founded by the father of the current owner and President in Akron in the early 1950's. It moved to the present site in April 1967.

The Company is proud of its record of manufacturing stamping tools and stamped and machined components mainly to the tire molding industry with some supply to the aerospace and medical industries. The tooling is produced using EDM wire erosion and conventional machining techniques. The majority of the components that the Company supplies are stamped, lasered and machined. The remaining parts are turned and milled. And others are created using Direct Metal Laser Sintering (DMLS)

It manufactures all of its products to specific customer order(s) and is noted for its rapid response to its customers' requirements. Any finished stocks held by the Company are the result of deliberate production overruns and these are only retained for specified periods. The Company's customers are 90% in the tire molding industry and they are located throughout the United States and overseas.

Acro Tool & Die manufactures its products to its customers' drawings and specifications and any external national specifications that may be required. The status of the Company in its chosen field for the provision of a professional product is well established. The Company also provides a high-quality service to the local business community.

In support of its status in this chosen field, the Company is a member of the National Tool & Die Association and operates to this organization's codes of practice.

An essential requirement of the Company is the development and continuous improvement of the quality system registered to ISO 9001:2015 and ISO 13485:2016 status. This will ensure the continuing effectiveness of the core principles of Acro Tool & Die.

In an effort to expand into new markets, The Company launched a new business arm and in May of 2020 began Doing Business As (DBA) Metalcraft Solutions.

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# **Quality Policy**

Acro / Metalcraft Solutions recognizes that the disciplines of quality, health and safety and environmental management are an integral part of its management function. The Company views these as a primary responsibility and to be the key to good business in adopting appropriate Quality standards.

The Company Quality Policy calls for continuous improvement in its Quality management activities and business will be conducted according to the following principles:

We will :

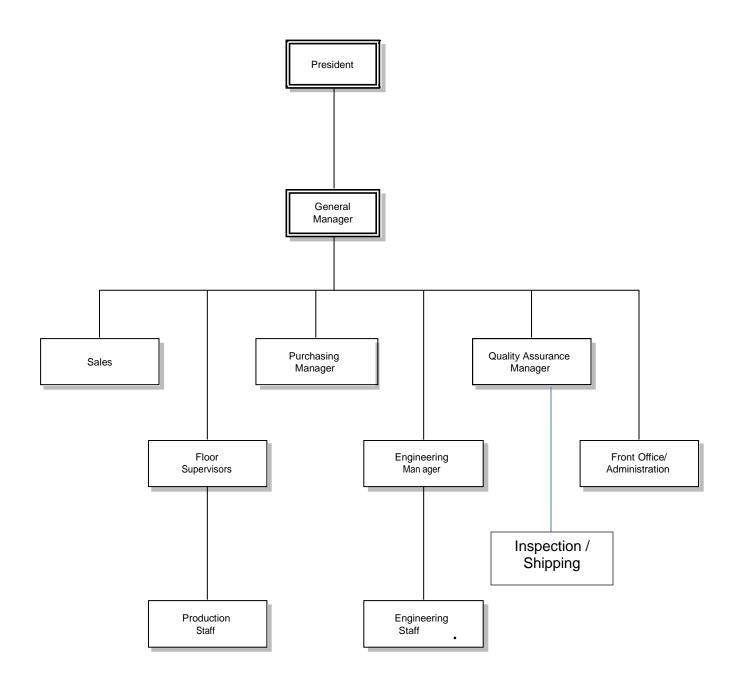
- Comply with all applicable statutory and regulatory requirements.
- Follow a concept of continuous improvement and make best use of its management resources in all Quality matters.
- Communicate its Quality objectives and performance against defined objectives throughout the Company and to interested parties.
- Take due care to ensure that activities are safe for employees, associates and subcontractors and others who come into contact with our workplace
- Work closely with our customers and suppliers to establish the highest Quality standards.
- Adopt a forward-looking view on future business decisions which may have Quality impacts.
- Train our staff in the needs and responsibilities of Quality management.

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# **Quality Objectives**

- Maintain Quality System certifications to ISO 9001 and ISO 13485.
- Keep number of annual Customer Complaints at or below 2.25% of number of all jobs produced.
- Maintain average monthly combined On-time delivery performance at 90.0%.
- Strive for Final Inspection pass rate at or above 98.25% of all part numbers produced
- Maintain average number of Lost Shop Hours at 135 or less per month.
- Develop formalized In-process Inspection program and begin tracking results by end of 2<sup>nd</sup> Quarter.

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### **Duties and Responsibilities**

#### **President**

- Company strategy
- Business development

#### General Manager

- Company strategy
- Business development
- Sales
- Customer liaison
- Sales order processing
- Operations

#### <u>Sales</u>

Sales order processing

#### Purchasing Manager

- Purchasing
- Material control
- Stocks

#### **Quality Assurance Manager**

- Quality Assurance
- Quality Management Representative
- Shipping

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### Engineering Manager

• Technical assistance

### Front Office/Administration

- General administration
- Payroll
- Invoicing
- Bookkeeping
- Credit control

### Production Manager

- Production Scheduling
- Safety

### Floor Supervisors

- Production
- Safety
- Maintenance

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In accordance with the procedures laid down in the authorized Quality Manual and the authorized Procedures Manual, the following are appointed as Quality Representative and Quality Auditors:-

### **QUALITY MANAGER / QUALITY REPRESENTATIVE**

**Eric Patterson** 

QUALITY AUDITOR

### Eric Patterson

QUALITY AUDITOR

### Eric Patterson

Signatures on File

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#### 4 <u>Quality Management System</u>

#### 4.1 General Requirements

Acro / Metalcraft Solutions through the offices of the President, is committed to maintaining an effective Quality Management System by meeting customer and applicable statutory and regulatory requirements.

#### 4.2 **Documentation Requirements**

The Company has written its Quality Policy and Procedures as appropriate to its size, type and complexity and it is available to all employees.

#### 4.2.1 General

The effective continuous improvement of the Quality Management System will be verified by regular inspections, reviews and audits that will compare management practice against the requirements of the written procedures. Corrective action will be taken where necessary and will be subsequently reviewed for effectiveness.

#### 4.22 Quality Manual

This manual has been prepared to satisfy the requirements of ISO 9001:2015 and ISO 13485: 2016

#### 4.23 Control of Documents

The Company has established procedures for the control of documents in the Procedures Manual according to ISO9001: 2015 and ISO 13485: 2016

#### 4.24 Control of Records

The Company control records to provide evidence of requirements and of the effective operation of our Quality Management System. All such records are kept legible, readily identifiable and retrievable.





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# QMS Requirements

### 5 <u>Management Responsibility</u>

### 5.1 Management Commitment

Top management of the Company ensures that all employees are aware of the need to meet Customer, applicable statutory and regulatory requirements and that the necessary resources are available. The currency of Quality Policy and objectives are maintained by regular management review.

### 5.2 Customer Focus

Customer needs and expectations are determined, and fulfilled to meet Customer satisfaction. Due consideration is given to product, service regulatory and applicable statutory requirements.

#### 5.3 Quality Policy

The Company has established, through its Quality Policy, the need to meet requirements and continually improve its products and services. Quality objectives are reviewed for continuing suitability and communicated as appropriate throughout the organization.

#### 5.4 Planning

#### 5.4.1 Quality Objectives

The Company has established that all relevant functions and levels within the Organization have clear, measurable quality objectives that are consistent with the Company Quality Policy and product requirements.

#### 5.4.2 Quality Management Systems Planning

Adequate resources are available and output is planned in a controlled manner as is required by its Quality Management System, being mindful of the process and the need for continual improvement.



#### 5.5 Responsibility, Authority and Communication

#### 5.5.1 Responsibility and Authority

Details of the Company Quality Management System are documented. Elements of the Quality Management System have been defined and communicated wherever quality is affected.

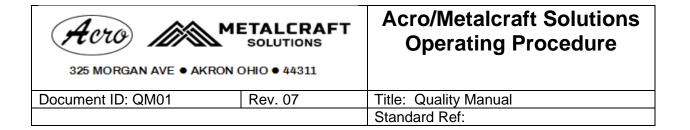
#### 5.5.2 Management Representatives

Representatives have been appointed from within the organization; that has the authority and responsibility to ensure that the Quality Management System is established and maintained and that reports on the performance of the system and any needs for improvement are made available to the Quality Representative. The significance of meeting Customer requirements is understood.

#### 5.5.3 Internal Communication

Communication between all levels and functions are set to ensure the effectiveness of the processes of the Quality Management Systems. The Company has prepared and maintains a controlled Quality Manual that defines the scope of its activities supported by referenced documented procedures and how the procedures operate.

A documented procedure ensures that all relevant quality documentation is controlled and adequate and is reviewed, updated and approved as necessary. The status of the documents is identified and they are legible and retrievable and located where required within the organization. Where documents originate from outside the organization they are identified and their distribution controlled and obsolete documents are clearly identified to prevent unintended use.



#### 5.6 Management Review

#### 5.6.1 General

The complete Quality Management System is reviewed at planned intervals to ensure its continuing suitability, adequacy and effectiveness to evaluate the need for change.

#### 5.6.2 Review Input

The review includes the evaluation of current performance and improvement opportunities related to audits, Customer feedback, process and product performance, follow up from previous meetings, and any changes that could affect product or service quality.

#### 5.6.3 Review Output

The results of activity arising from review meetings where resources, the Quality Management System and its processes and improvements to products related to Customer requirements are discussed, is an essential part of the review process. All results of management review activities are recorded.





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### 6 <u>Resource Management</u>

### 6.1 **Provision of Resources**

The Company has ensured that the necessary resources needed to implement and improve the quality management system and to address Customer satisfaction are available.

#### 6.2 Human Resources

#### 6.2.1 General

When staffs are assigned, responsibilities affecting product conformity, the Company has determined the necessary competence for personnel performing the work.

#### 6.2.2 Competence, Training and Awareness

The Company has identified the training needs for quality related activities and provides training to achieve the necessary competence. Performance is evaluated and appropriate training records are maintained.

#### 6.3 Infrastructure

Suitable equipped workplaces with appropriate hardware and software with supporting services such as transport, communication or information systems.

#### 6.4 Work Environment

All aspects of the human and physical factors of the working environment that affect conformity of product or service have been identified and are managed.



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# **QMS** Requirements

#### 7 **Product Realization**

#### 7.1 **Planning of Realization Process**

The production process for the Company's products and services is planned and documented as defined in the Quality Management System. Quality objectives, resources, processes and documentation needs are defined and acceptable criteria for verification and validation are determined. Records appropriate to the level of confidence required for the process and the product or service are maintained

#### 7.2 Customer Related Processes

### 7.2.1 Determination of Requirements Related to the Product

SOLUTIONS

The needs of the Customer in respect of availability, delivery and support are considered against the product's intended use, and regulatory and applicable statutory requirements are determined and implemented.

#### 7.2.2 Review of Requirements Related to the Product

The Company reviews its customers' requirements and determines any additional requirements for each contract or order. Where no Customer requirements are documented, details are confirmed before acceptance. Any changes to contracts or quotations are resolved before proceeding and the Company's ability to meet the defined requirements is confirmed.

#### 7.2.3 Customer Communication

The Customer is kept informed of product information, inquiries, order changes or amendments and progress on Customer complaints.

#### 7.3 **Design and/or development**

#### No design or development activity is carried out by the Company; therefore, this clause is not applicable.

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### 7.4 Purchasing

#### 7.4.1 Purchasing Process

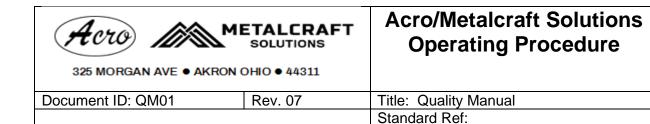
The Company controls its purchasing function to ensure that the purchased product conforms to requirement. Suppliers are selected against defined criteria and are subject to planned review and evaluation. The results of evaluations and follow up actions are recorded.

#### 7.4.2 Purchasing Information

Purchasing documents are reviewed before release for the adequacy of information on product, procedures, processes, equipment and personnel.

#### 7.4.3 Verification of Purchased Product

The Company verifies its purchased products and where verification takes place at the supplier's premises, details of the arrangements and the method of release are specified.



#### 7.5 **Production and service Provision**

#### 7.5.1 Control of Production and Service Provision

Production and services are controlled through product specifications and work instructions. Suitable equipment is used and properly maintained with the use of specified measuring and monitoring equipment and activities. Product release and post-delivery and delivery processes are defined.

#### 7.5.2 Validation of Process for Production and Service Provision

Where appropriate, the Company identifies the product throughout the production and service activities and identifies its status with respect to measuring and monitoring activity throughout product realization. Where traceability is required, the unique identification of the product is controlled and recorded.

#### 7.5.3 Identification and Traceability

Where Customer property for inclusion in the product comes within the Company control, it is identified, verified, maintained and protected with details of adverse condition reported to the Customer.

#### 7.5.4 Customer Property

The Company preserves the conformity of the product or service from receipt of order to delivery.

#### 7.5.5 Preservation of Product

Where verification of product or service cannot be ensured during the process by measuring and monitoring, control is exercised by qualification of the process, equipment and personnel through defined methods procedures and records and revalidation if required.



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### 7.6 Control of Measuring and Monitoring Equipment

Measuring and monitoring equipment and software are identified throughout the Company. The equipment/software used is controlled to appropriate standards. The equipment is protected against random adjustments, damage and deterioration and the results of calibrations are recorded. The software is password protected.

#### 8 Measurement, Analysis and Improvement

### 8.1 General

The requirement for measurement and monitoring devices has been determined and the method of use.

#### 8.2 Measurement and monitoring

#### 8.2.1 Customer Satisfaction

Clear methods have been established to audit Customer satisfaction and any failures to meet Company standards.

#### 8.2.2 Internal Audit

Suitably trained and impartial personnel conduct periodic independent internal audits on a planned basis. All aspects of internal audits are recorded and reviewed and corrective action taken where necessary.



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# **QMS** Requirements

#### 8.2 Measurement and monitoring (cont.)

### 8.2.3 Monitoring and Measurement of Processes

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Processes affecting Customer requirements are periodically reviewed to ensure that the intended purpose is being met.

#### 8.2.4 Monitoring and Measurement of Product

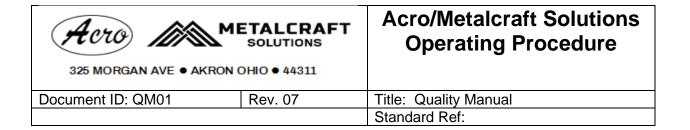
Measuring and monitoring of the product throughout the process is designed to ensure the finished item meets specification and authorized personnel control its release.

#### 8.3 **Control of Nonconformity**

Documented procedures are in place to identify and isolate non-conforming products and, before repaired product is returned to the process, it is re-checked. In the event of non-conforming product reaching the Customer appropriate corrective action is taken.

#### 8.4 Analysis of data

Data referring to product quality problems are collected and analyzed and, where changes to the quality management system offer improvements, these changes are introduced. Areas for attention are Customer complaints, meeting the Customers' needs, product characteristics and supplier performance.



#### 8.5 Improvement

#### 8.5.1 Continual Improvement

The Quality Management System is managed in a manner to offer continual improvement having regard to statements in its Quality Policy, objectives, audit results, data analysis, corrective and preventive action and management review.

#### 8.5.2 Corrective Action

Appropriate action is taken to rectify faults and prevent their recurrence and the procedure is documented. Requirements for identifying faults and determining their cause with appropriate corrective action is covered, recorded and the results are reviewed for effectiveness.

#### 8.5.3 **Preventive Action**

The Company identifies preventive actions to prevent the recurrence of nonconformities and the results of such actions are recorded and reviewed for effectiveness.